Guidance for Industry

FREQUENTLY ASKED QUESTIONS ON THE NEW 510(k) PARADIGM

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Program Operations Staff
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Heather Rosecrans at HFZ-404. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact Ms. Rosecrans at (301) 594-1190 or E-mail: hsr@cdr.fda.gov.

Additional Copies

Additional copies: World Wide Web/CDRH home page: http://www.fda.gov/cdrh/ode/qanda510k.pdf ,CDRH Facts on Demand at 1-800-899-0381, or (301)-827-0111, specify number 2230 when prompted for the document shelf number

FREQUENTLY ASKED QUESTIONS ON THE NEW 510(k) PARADIGM

On March 20, 1998, the Center for Devices and Radiological Health (CDRH) announced the availability of a guidance document entitled, "The New 510(k) Paradigm -- Alternatives to Demonstrating Substantial Equivalence in Premarket Notification Submissions." In this guidance, two new alternatives to the traditional approach of demonstrating substantial equivalence were discussed. Both alternatives, i.e., the Special 510(k) and the Abbreviated 510(k), were designed to provide flexibility to the device industry, conserve Agency and industry resources, and optimize the contribution of the 510(k) Program to the protection of public health.

Based on the Agency's and industry's experience with the Guidance, the Center has developed the following questions and answers. These should serve to clarify certain aspects of the document, specifically declarations of conformance to design controls and standards, and to promote consistency in the use of the Guidance. This question and answer document[1] will be updated on a periodic basis to include frequently asked questions and/or to provide the Agency's perspective on specific issues of the Paradigm. Interested persons can submit questions for inclusion in future revisions by calling Ms. Heather Rosecrans at (301) 594-1190 or submitting their questions via the Internet to hsr@cdrh.fda.gov.

At the end of this question and answer document, an example of a Special 510(k) for a cardiovascular catheter and a guidance document to be used in preparing an Abbreviated 510(k) for a latex condom can be found. These documents were developed with the aid of the regulated industry to help illustrate the two new alternatives to the Traditional 510(k). Comments on these examples are welcome and may be submitted to the above Internet address.

General Questions

1. **Are Special and Abbreviated 510(k)s eligible for review under the Agency's Third Party Pilot Program?**

   Both Special and Abbreviated 510(k)s may be reviewed under the Third Party Pilot Program as long as the 510(k)s are for devices that are included in that program. Given that the Agency has committed to a 30 day review of Special 510(k)s, however, there may be no real advantage to using Third Parties to review this particular type of submission.

[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Note: Manufacturers should not confuse the review of select 510(k)s by Third Parties with third party involvement in assessing conformance with design controls or standards. This latter topic is discussed in more detail in response to question #4.

2. **Can FDA rely on a declaration of conformity for a substantial equivalence determination in an Abbreviated or Special 510(k) if the manufacturer states that they will conform rather than they are in conformance?**

The Food and Drug Administration Modernization Act of 1997 added section 514 (c*) Recognition of a Standard* to the Federal Food Drug and Cosmetic Act (the act). According to this section of the act, a declaration of conformity to a recognized standard must certify that the device is in conformance. Therefore, in order for the Center to rely upon a declaration of conformity to a standard in making a substantial equivalence (SE) determination in an Abbreviated 510(k), the declaration must indicate that the submitter is in conformance. The Agency has adopted this same approach for Special 510(k)s. That is, a manufacturer may not state that they will conform at some future date, but rather conformance must have already been determined at the time the application is submitted.

It should be noted that declarations indicating that a device/firm will conform to a standard/design controls has been the most common reason that a submission has not been accepted for review as either an Abbreviated or Special 510(k), respectively.

3. **What happens if an Abbreviated 510(k) includes a statement indicating that the device will conform but is not yet in conformance with a standard?**

As stated above, for issues material to the substantial equivalence determination, the Agency would not be able to rely upon such a statement. A declaration of conformity certifying that the device is in conformity to the standard would be needed.

The only exception to the above would be for cases where substantial equivalence had previously been demonstrated for devices of this type without conformance to the standard. For example, if a manufacturer states that a device will conform to IEC-60601-1-2 Electromagnetic Compatibility and substantial equivalence for the predicate device had been determined without conformance to the standard, then the submission could be reviewed as an Abbreviated 510(k). If, as stated above, conformance to this standard is integral to the SE determination, then conformance would need to be established before the 510(k) is submitted.

4. **What advantage, if any, is there for a firm to use a third party to assess conformance with design controls or recognized standards? If a firm does use a third party for the assessment, should this information be included in the 510(k) submission?**

Many device manufacturers employ third parties in assessing conformance with design controls or standards as a matter of routine practice. Although it is ultimately the submitter's responsibility for assuring conformance when electing to submit a declaration of conformity in a premarket submission, third party involvement may provide the

manufacturer with added confidence when submitting a declaration and provide the Agency with additional assurance of conformance. Involvement by an independent, technically competent third party can only benefit the overall process. In The New 510(k) Paradigm, it is stated that if a manufacturer uses a third party to perform a conformance assessment of design control requirements or standards, this information should be maintained in the firm's device master record (DMR). In Attachment 4 of the document, however, it is stated that the declaration to conformity to a recognized standard should include the name and address of any test laboratory or certification body involved in the conformance assessment as well as a reference to the accreditation of the third party. To clarify this issue, the Agency recommends that 510(k) submitters follow Attachment 2 and 4, when preparing declarations of conformity to design controls and standards, respectively. Thus, declarations of conformity to standards should include the name, address, and accreditation of all third parties involved in the conformance assessment. Declarations of conformity to design controls, however, would not need to include this information.

5. **What happens if the Agency determines that a Special or an Abbreviated 510(k) can not be reviewed as such? Is the submission rejected? Is the review clock reset?**

If the Agency determines that a Special or an Abbreviated 510(k) is not eligible for review as submitted, the reviewer will notify the firm of this decision and offer the option of having the document converted to a Traditional 510(k) or withdrawing it for future submission. If the 510(k) is converted, the original receipt date remains as the start of the review period. Manufacturers should be aware that, in most cases, additional information will be necessary for converted documents.

Questions Related to Special 510(k)s

1. **For Special 510(k)s, Attachment 2 of the guidance document states that the manufacturer's declaration of conformity should include a statement that "all verification and validation activities were performed.…" Since some of these activities are not usually performed until just prior to marketing, what activities should be performed prior to submission of the Special 510(k)?**

This statement in the declaration of conformity is intended to capture the manufacturer's compliance with those verification and validation activities that are related to the design modification(s). Therefore, prior to submission of a Special 510(k), FDA would expect that the verification and validation activities, as identified by the risk analysis to ensure that the modified device is as safe and effective as the predicate device, would be completed and would demonstrate that the predetermined acceptance criteria had been met. In accordance with the Quality System Regulation, however, all process validation must be completed and appropriately documented before commercialization of the device.

2. **If a firm obtains clearance for a Special 510(k), will the firm necessarily be inspected to verify conformance with design controls?**

No. The Office of Compliance is developing an audit program to help determine if firms that submitted Special 510(k)s were in fact in conformance with design control requirements. This does not mean, however, that all firms that submit Special 510(k)s will be audited. Under the pilot program, a limited number of cleared submissions will be identified for verification of conformance with design controls by inspection. If a firm is to be inspected, the Agency will notify the firm ahead of time and follow established GMP inspection procedures.

Having stated the above, manufacturers are reminded that routine GMP inspections for Class II and III devices are required by the statute. Thus, submitters of 510(k)s for such devices are subject to inspection whether the premarket notification is submitted for review as an Abbreviated, a Special, or a Traditional 510(k).

3. **For Special 510(k)s that were submitted but later determined to be ineligible for review as such, what were the most common reasons for this determination?**

The most frequently observed problem with Special 510(k)s has been related to the design control information that was submitted in support of the device modification. Several submissions did not include a complete declaration of conformity to design controls. Other submissions included a statement indicating that the firm would comply with the design control requirements rather than a statement that the firm is in conformance. In a few 510(k)s, it was determined that the firm did not perform a complete risk analysis for the device modification.

Finally, one of the other problems observed with the Special 510(k)s that have been submitted for review has been related to the device modification that is the subject of the submission. As discussed in the Guidance, changes to the intended use and fundamental scientific technology should be submitted as Abbreviated or Traditional 510(k)s rather than as Special 510(k)s. Several of the Special 510(k)s that were submitted included a change to either the intended use or to the fundamental scientific technology.

Question Related to Abbreviated 510(k)s

1. **How many standards has FDA recognized? Where can the current list of recognized standards be found?**

FDA has recognized approximately 400 standards to which 510(k) submitters can declare conformity. The list of these standards can be found at on the World Wide Web at: www.fda.gov/cdrh/modact/recstand.html. The Agency will update this list on a periodic basis.

2. **Is the 30 day review clock for Special 510(k)s also applicable to Abbreviated 510(k)s?**

No. While the Agency expects that declarations of conformity to standards will reduce the review time for Abbreviated 510(k)s compared to Traditional 510(k)s, FDA did not establish a 30 day review clock for Abbreviated 510(k)s.

3. **Could a submitter be held liable if a declaration of conformity to a standard is based on information that turns out to be false? What if the information was provided to the submitter by a third party? What are the consequences of submitting a false declaration of conformity?**

Yes. Submitting a false declaration of conformity to a standard is specifically identified as a prohibited act in section 301(x) of the act. If it is determined that the information underlying the declaration of conformity is false or misleading in any material respect, the submitter of the declaration could be held liable. This is true whether the information was generated by the submitter or by a third party (e.g., a testing facility). Therefore, it is important that a person declaring conformity to a standard carefully review the information forming the basis for the declaration before it is submitted to the Agency.

Having stated the above, the Agency does wish to distinguish a "false" or "misleading" declaration of conformity from a declaration of conformity in which FDA disagrees with the adequacy of the supporting data. The Agency acknowledges that a manufacturer may make a good faith effort to conform with a standard and yet FDA may disagree with the basis upon which the declaration was made. Under such circumstances, the Agency will make every effort to resolve the issue with the submitter.

4. **During the review of a 510(k), does FDA anticipate that it will routinely ask for the data or information supporting a declaration of conformity to a standard?**

Section 514 of the act authorizes the Agency to request, at any time, data or information relied upon for the declaration of conformity. FDA does not, however, expect that this would routinely occur, but rather only on a case-by-case basis if a serious concern arises during the review of the submission. The concurrence of senior management would be needed before such a request would be made.

5. How long should the records supporting a declaration of conformity to a standard be maintained?

Section 514 of the act requires persons declaring conformity to a standard to maintain data and information demonstrating conformity of the device to the standard for two years after the date of the substantial equivalency determination or for a period equal to the expected design life of the device, whichever is longer.

For additional questions and answers on the use of recognized standards in premarket submissions, please see "Frequently Asked Questions on Recognition of Consensus Standards" which can be found at: www.fda.gov/cdrh/modact/faqost.html.

Special 510(k): Device Modification

[Date of Submission] *[Company Letterhead]*

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Reference : *[List Original 510 (k) number, trade name and date of concurrence]*

Dear Madam/Sir:

The *[Company Name]* hereby submits this **Special 510(k): Device Modification** to request a modification for our Angiographic Catheters. The modification is to change the hub/shaft bonding process and add a 7F catheter line. We believe these modifications are eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device.

We consider our intent to market this device as confidential commercial information and requests that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intend to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at *[Phone Number]*.

Sincerely,

[Name of Submitter]
[Title]

Special 510 (k) - Angiographic Catheter Modification

Table of Contents

Attachments

CDRH SUBMISSION COVER SHEET	
Date of Submission:	FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modules submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trails ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☐ Original submission ☐ Traditional ☐ Special ☐ Abbreviated ☐ Additional information ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code): ( )
Street address:		FAX number (include area code): ( )
City:	State/Province:	Country:
Contact name:		
Contact title:		Contact e-mail address:

Section C Submission correspondent (if different from above)

Company/Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code): ( )
Street address:		FAX number (include area code): ( )
City:	State/Province:	Country:
Contact name:		
Contact title:		Contact e-mail address:

Section D1 Reason for Submission - PMA, PDP, or HDE

- ❑ New device
- ❑ Withdrawal
- ❑ Additional or expanded indications
- ❑ Licensing agreement

- ❑ Change in design, component, or specifications:
  - ❑ Software
  - ❑ Color Additive
  - ❑ Material
  - ❑ Specifications
  - ❑ Other (specify below)

- ❑ Location change:
  - ❑ Manufacturer
  - ❑ Sterilizer
  - ❑ Packager
  - ❑ Distributor

- ❑ Process Change:
  - ❑ Manufacturing
  - ❑ Sterilization
  - ❑ Packaging
  - ❑ Other (specify below)

- ❑ Labeling change:
  - ❑ Indications
  - ❑ Instructions
  - ❑ Performance characteristics
  - ❑ Shelf Life
  - ❑ Trade Name
  - ❑ Other (specify below)

Report submissions:

- ❑ Annual or periodic
- ❑ Post-approval study
- ❑ Adverse reaction
- ❑ Device defect
- ❑ Amendment

- ❑ Response to FDA correspondence:
  - ❑ Request for applicant hold
  - ❑ Request for removal of applicant hold
  - ❑ Request for extension
  - ❑ Request to remove or add manufacturing site

- ❑ Change in ownership
- ❑ Change in correspondent

- ❑ Other reason (specify):

Section D2 Reason for Submission - IDE

- ❑ New device
- ❑ Addition of institution
- ❑ Expansion/extension of study
- ❑ IRB certification
- ❑ Request hearing
- ❑ Request waiver
- ❑ Termination of Study
- ❑ Withdrawal of application

- ❑ Unanticipated adverse effect
- ❑ Notification of emergency use
- ❑ Compassionate use request

- ❑ Treatment IDE
- ❑ Continuing availability request

- ❑ Other reason (specify):

- ❑ Change in:
  - ❑ Correspondent
  - ❑ Design
  - ❑ Informed Consent
  - ❑ Manufacturer
  - ❑ Manufacturing process
  - ❑ Protocol - feasibility
  - ❑ Protocol - other
  - ❑ Sponsor

- ❑ Report Submission:
  - ❑ Current investigator
  - ❑ Annual progress
  - ❑ Site waiver limit reached
  - ❑ Final

- ❑ Response to FDA letter concerning:
  - ❑ Conditional approval
  - ❑ Deemed approved
  - ❑ Deficient final report
  - ❑ Deficient progress report
  - ❑ Deficient investigator report
  - ❑ Disapproval
  - ❑ Request extension of time to respond to FDA
  - ❑ Request meeting

Section D3 Reason for Submission - 510(k)

- ❑ New device
- ❑ Addition or expanded indications

- ❑ other reason (specify):

- ❑ Change in technology
- ❑ Change in design

- ❑ Change in materials
- ❑ Change in manufacturing process

Section E Additional Information on 510(k) Submissions				
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:
1	2	3	4	❑ 510 (k) summary attached ❑ 510 (k) statement
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information - Applicable to All Applications

Common or usual or classification name:

Trade or proprietary or model name	Model number
1	
2	
3	
4	
5	

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission : ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Section G Product Classification - Applicable to All Applications

Product code:	C.F.R. section	Device class: ☐ Class I ☐ Class II ☐ Class III ☐ Unclassified

Classification panel:

Indications (From labeling):

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing/ Packaging / Sterilization Sites

❑ Original ❑ Add ❑ Delete	FDA establishment registration number:	❑ Manufacturer ❑ Contract sterilizer ❑ Contract manufacturer ❑ Repackager/relabeler	
Company/institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		Fax number (include area code):	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact Name:			
Contact Title:		Contact e-mail address:	
❑ Original ❑ Add ❑ Delete	FDA establishment registration number:	❑ Manufacturer ❑ Contract sterilizer ❑ Contract manufacturer ❑ Repackager/ relabeler	
Company/institution name:		Establishment registration number:	
Division name (if applicable): N/A		Phone number (include area code): ( )	
Street address:		Fax number (include area code): ( )	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact Name:			
Contact Title:		Contact e-mail address:	

Device Name

The device trade names and common/classifications names are:

Device Trade Name	Common/Classification Name
[Trade Name]	Angiographic Catheter

Address and Registration #

The address and registration number of the manufacturer and sterilization sites for both catheters are:

Manufacturer	Sterilization Site
[Company Name] *[Company Address]* FDA Registration #: *[Number]*	*[Company Name]* *[Company Address]* FDA Registration #: *[Number]*

Device Class

Angiographic catheters have been classified as Class II, 74 HBY. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Angiographic catheters.

Predicate Device Information

The predicate device is the *[Trade Name]* Angiographic Catheter, *[510 (k) Number, concurrence date]*.

Labeling and Intended Use

Draft labels and Instructions for Use can be found in Attachment 1.
[Make statement that no changes to the labels or Intructions for Use have occurred or identify what changes have been made].

Intended Use

The *[Trade Name]* Angiographic Catheters intended use are for the delivery of diagnostic agents in the intravascular system. This is the **same intended use** as previously cleared for the *[Trade Name]* Angiographic Catheter , *[510 (k) Number]*.

The Indications for Use statement can be found in Attachment 2.

Continued on next page

Device Description and Comparison

The device description of the *[Trade Name]* Angiographic Catheters is as follows.

- 4 - 7 French
- 50 - 150 cm length
- Polyurethane hub insert molded to a braided nylon shaft.
- Maximum burst pressure of 1200 psi
- .038" maximum guidewire diameter

The only modifications that were made are:

1. Change the hub/shaft bonding process from an adhesive bond to insert molding.
2. Expand the product line from 4, 5, & 6F to add a 7F version catheter.

*[**Note:** Before and after statements are recommended by FDA to clarify the modifications being made].*

Substantial Equivalence

The modified angiographic catheters have the following similarities to those which previously received 510(k) concurrence:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic catheter design,
- incorporate the same materials,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

*[**Note:** Listing the similarities is optional, however, it may reduce the need for the reviewer to verify this information in the previous submission].*

In summary, the *[Trade Name]* Angiographic catheters described in this submission are, in our opinion, substantially equivalent to the predicate device.

Continued on Next Page

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA).[2] The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 1 below.

TABLE 1 - Verification Tests

Modification	Test Performed	Acceptance Criteria
Change Hub/Shaft Bond Process	• hub/shaft pull strength test	• 1.0 lbs
Addition of 7F Product Line	• dimensional inspection • hydrostatic pressure test • flow rate test	• per drawing • 1200 psi • >5ml/sec

The test methods used are the same as those submitted in the original submission.

A declaration of conformity with design controls is included in Attachment 3.

510(k) Statement

A 510(k) Statement for the *[Trade Name]* Angiographic Catheters is included in Attachment 4.

*[**Note:** This can be replaced by a 510 (k) summary].*

Truthful and Accuracy Certification

A certification of the truthfulness and accuracy of the *[Trade Name]* Angiographic Catheters described in this submission is provided in Attachment 5.

End

[2] Manufacturer should list which risk analysis method was used.

Attachment 1

Labels and IFU's

Attachment 2

Indications for Use Statement

510(k) Number (if known)

Device Name *[Trade Name]* Angiographic Catheter

Indications for Use The *[Trade Name]* Angiographic Catheter intended use is for the delivery of diagnostic agents in the intravascular system.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Attachment 3

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

_____ _____

[Name] *[Date]*
[Title]
[Company]

Manufacturing Facility

The manufacturing facility, *[Company Name]* is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

_____ _____

[Name] *[Date]*
[Title]
[Company]

[NOTE: The above two statements should be signed by the designated individual (s) responsible for those activities].

Attachment 4

510 (k) Statement

Statement

I certify that, in my capacity as (the position held in company by the person required to submit the premarket notification, preferably the official correspondent), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

[Signature of certifier]

[Typed Name]

[Dated]

Attachment 5

Truthful and Accuracy Statement

Pursuant to 21 CFR 807.87(j), I *[Name]*, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as *[The position held in Company]* of *[Company Name]*, and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

_____

[Signature]

_____

[Typed Name]

_____

[Dated]

Guidance for Industry

Latex Condoms for Men

Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions

Document issued on: July 23, 1998

U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Obstetric and Gynecology Devices Branch
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Colin M. Pollard, Chief, Obstetrics and Gynecology Devices Branch (OGDB), HFZ-470, 9200 Corporate Blvd., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact Mr. Colin M. Pollard at 301-594-1180 or by electronic mail, at cmp@cdrh.fda.gov.

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World Wide Web/CDRH home page: http://www.fda.gov/cdrh, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1250 when prompted for the document shelf number.

This guidance document represents the agency's current thinking on the use of consensus standards for abbreviated submissions for 510(k) Premarket notifications for latex condoms for men. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Latex Condoms for Men
Information for 510(k) Premarket Notifications:
Use of Consensus Standards for Abbreviated Submissions

Section 510(k) of the Act and the implementing regulation, 21 CFR Part 807, require persons who intend to market a new device to submit a premarket notification containing information that enables FDA to determine whether the new device is substantially equivalent within the meaning of Section 513(i) of the Act to a legally marketed device that does not require premarket approval. Unless exempted from premarket notification requirements, persons may not market a new device under Section 510(k) of the Act, unless they receive a substantial equivalence order from FDA or an order reclassifying the device into Class I or Class II (section 513(i) of the Act). Male condoms are classified as Class II devices under 21 CFR §884.5300 and §884.5310 (Condom with spermicidal lubricant) and are not exempted from 510(k) requirements, therefore, a 510(k) premarket notification must be cleared by order of FDA before a new male condom, or one that has been significantly changed or modified, is introduced into interstate commerce.

A person required to submit a 510(k) premarket notification must provide information as required by the statute and regulations to allow the Center to make an appropriate decision regarding the clearance of the submission.

The Center believes that conformance with recognized consensus standards can provide a reasonable assurance of safety and/or effectiveness for many aspects of medical devices, including Male Latex Condoms. A 510(k) that contains a declaration of conformity to recognized consensus standards, as discussed below, will, in most cases, eliminate the need to review the actual test data for those aspects of the device addressed by the standards. This, however, does not affect the Center's ability to obtain any information authorized by the statute or regulations. Conformance with recognized consensus standards in and of itself may not always be a sufficient basis for regulatory decisions. For example, a specific device and/or intended use may raise safety or effectiveness issues not addressed by any recognized consensus standard, or a specific FDA regulation may require additional information beyond what conformity to recognized consensus standards provide. Under such circumstances, conformity with recognized standards will not satisfy all requirements for marketing the latex condom in the United States.

The Center for Devices and Radiological Health has recognized and will use consensus standards pursuant to the Food and Drug Administration Modernization Act of 1997 (P.L. 105-115), which amends section 514 of the Food, Drug, and Cosmetic Act (21 U.S.C. 514(c)). FDA has recognized voluntary consensus standards for Latex Condoms for Men, and other relevant standards may also be applicable to the submission of a 510(k) for a latex condom, *e.g.*, ISO 10993. A list of recognized standards is maintained on the CDRH website and is updated at least annually. Other recognized standards may be applicable for latex condoms and **manufacturers have the right to make a declaration of conformity to any listed standard.** *[FDA Guidance on the Recognition and Use of Consensus Standards,* February 19, 1998, q.v.]

Building on FDA's recognition of the ASTM voluntary consensus standard for condoms and the ISO voluntary consensus standard for biological evaluation of medical devices, this guidance document provides an outline for a 510(k) premarket notification that incorporates a declaration of conformance with these standards. When the declaration is combined in a 510(k) which is complete and accurate, it can serve as the basis for an FDA finding of substantial equivalence for a Natural Rubber Latex (NRL) Condom. (Other criteria exist for blends and non-NRL Male Condoms and for Female Condoms.)

<< Cover Letter >>

[Date of Submission]

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: Abbreviated 510(k) Notification
***[Brand Name]* Male Latex Condom**

Dear Sir or Madam:

This submission is being made in compliance with Section 510(k) of the Food, Drug and Cosmetic Act as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997, and the Office of Device Evaluation guidance for Abbreviated 510(k) requirements for a male latex condom. The enclosed information is being submitted for the *[Brand Name]* Male Latex Condom, which is made from Natural Rubber Latex. Two copies of this Premarket Notification are being submitted in accordance with 21 CFR 807.

The purpose of this submission is to notify FDA, in accordance with the 510(k) provisions of the Act, of our intent to introduce this *[new product, the…* /or/ *modification of the currently marketed] [Brand Name]* Male Condom into commercial distribution.

If you have any questions regarding this submission, please telephone *[contact person's name]* at *[(area) phone number]*.

Sincerely yours,

[*signature]*

[Name]

[Title]

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[Refer to §807.85(j)]

I certify, in my capacity as *[Title]*, that I believe, to the best of my knowledge, that all data and information submitted in this 510(k) Premarket Notification Submission is truthful and accurate and that no material fact has been omitted.

[signature]

……

[Name]

[Title]

[date]

……

Date

I. GENERAL INFORMATION

A. Submitter's Name and Address
[Company Name]
[P.O. Box & Street Address]
[City, State, ZIP]

B. Contact Person
[Name]
[Title]
[Phone]
[Fax]

C. Establishment Registration Number of Submitter
[Number]

D. Contract Manufacturing Facility
[Company Name & Address]
Establishment Registration: *[Number]*

E. Device Name
Proprietary Name:
Common Name:
Classification Name:

F. Device Classification
Class II §884.5300 and/or §884.5310 (Condom with spermicidal lubricant)

G. Action Taken to Comply with Section 514 of the Act
The Agency has recognized the ASTM Standard Specifications for Rubber Contraceptives (Condoms), D3492, and the ISO standard 10993: Biological Evaluation of Medical Devices. Conformance or variance with these standards is described on the following pages.

H. Reason for 510(k) Submission
q Initial Product Introduction
❑ New Model for Product-line Extension
❑ Initial Import into the USA
❑ Other (Include in Part IV an explanation referenced to Part I.H.)

I. Predicate Device
[Brand Name of Predicate Device]
[Company Name]
510(k) Document Control Number *[K######]*

NOTE: ***Provide the information required by 21 CFR §807.92, Content and format for a 510(k) summary (Option 1),***
<u>OR</u>
the 510(k) Statement (Option 2) on the next page.

II. 510(k) SUMMARY (Option 1)
[Refer to 21 CFR §807.92]

<u>Submitted by</u>: [*Company*]
[*Division*]
[*P.O. Box / Street Address*]
[*City, State Zip*]
[*Phone*]

<u>Contact Person</u>: [*Individual's Name*]

<u>Date Prepared</u>: [*Date*]

<u>Proprietary Name</u>: [*Brand Name of Condom*]

<u>Common Name</u>: Latex Condom

<u>Classification Name</u>: Condom (21 CFR §884.5300)
and / or
Condom with Spermicidal Lubricant (21 CFR §884.5310)

<u>Predicate Device</u>: Latex Lubricated Condom
510(k) #K[######]
and / or
Latex Condom with Spermicidal Lubricant
510(k) #K[######]

<u>Description of the Device</u>: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom [*include a brief description of the condom, such as, a straight-walled, nipple-end, nominal length, nominal width, nominal thickness, etc*].

<u>Intended Use of the Device</u>: This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)

<u>Technological Characteristics</u>: [*Indicate whether the condom has the same technological characteristics as the predicate condom identified above. Indicate that the design is in conformance with ASTM Latex Condom Standard D3492 and that the condom is made of natural rubber latex. Summarize the similarities and differences of the features and technological characteristics of the condom in comparison to the predicate condom.*]

II. 510(k) STATEMENT (Option 2)

[Refer to §807.93]

I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

.

Certified: _____*[Signed]*_____

_____*[Date]*_____

III. DECLARATION of CONFORMANCE with CONSENSUS STANDARDS

A. The condom intended to be introduced conforms in all respects with the requirements of the current edition of ASTM* Standard Specification for Rubber Contraceptives (Male Condoms), D3492, except as noted "at variance":

Requirement*	SO STIPULATED †	AT VARIANCE ‡
1. Manufactured from good quality natural rubber latex.(ammoniated), conforming to Specification ASTM D 1076-97	1. ☐	☐
2. Meets criteria that toxic, sensitizing, locally irritating, or otherwise harmful substances are not released or liberated	2. ☐	☐
3. Minimum length is 160 mm	3. ☐	☐
4. Maximum width is 54 mm	4. ☐	☐
5. Minimum thickness is 0.03 mm	5. ☐	☐
6. Air Burst Test Pressure	6. ☐	☐
7. Air Burst Test Volume	7. ☐	☐
8. Leakage AQL	8. ☐	☐
9. Package integrity AQL	9. ☐	☐

B. The condom intended to be introduced has been tested in conformance with the following test methods of ISO 10993 Biological Evaluation of Medical Devices and ODE Guidance Memorandum G95-1 dated May 1, 1995, for a Device in Contact for 24 hours or less with a Skin/Mucosal Membrane Surface, except as noted "at variance". When evaluated according to this standard, the condom is not toxic (local or systemic), sensitizing, locally irritating or otherwise harmful.

Requirement*	SO STIPULATED †	AT VARIANCE ‡
1. ISO 10993-5 — Cytotoxicity	1. ☐	☐
2. ISO 10993-10 — Irritation and Sensitization	2. ☐	☐
3. ISO 10993-11 — Systemic Toxicity	3. ☐	☐
4. ISO 10993-12 — Sample Preparation and Reference Materials	4. ☐	☐

The ISO 10993 standard describes test methods, but does not specify performance limits for each test. Therefore, data summaries and results of the above safety testing are included in Part IV.

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* ASTM — American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428; (610) 832-9500. Refer to full text of ASTM D3492 for the specific requirements that apply.

† Certifying signature required on next page of this Part.

‡ Include (under a separate section, identified with the item number) information, data, and analyses appropriately describing and explaining variance from standard; include rationale for variance and justification why this variance does not have a material impact on the substantial equivalence of the condom.

III. DECLARATION of CONFORMANCE with CONSENSUS STANDARDS
(continued)

C. This device is certified to comply with the voluntary standards as contained in ASTM D3492– *[insert edition date]* and ISO 10993– *[insert edition date]*, as specified and so stipulated above, unless and where specifically so indicated to be at variance with the standard specification, in which case information, data, and analysis, or justification for non-applicability, are provided to fully describe the variance and its impact on the device and to justify said variance.

[signature]
[Name]
[Title]

[Date]
Date

When there is a third-party certifying laboratory or certification body, provide the names and addresses and a reference to any accreditation of each laboratory. Certification statements should also be included.

IV. DESCRIPTION OF DEVICE

A. Description of the Device: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom [i*nclude a diagram(s) and a brief description of the condom, such as, a straight-walled, nipple-end, nominal length, nominal width, nominal thickness, dusting powder, lubricant systems, and other specifications. If a color additive is used, include a citation to the FDA Color Listing Regulation for the color and the Color Index Number*]. See example, Tabs 1 and 2.

B. Proprietary and Confidential Compounded Latex Formulation: [Provide a listing of the component ingredients and the range of quantities used in the preparation of the compounded latex.] See example, Tab 2.

C. Summary Reports of Safety Testing Results: [*Provide a summary of the results obtained from the cytotoxicity, irritation and sensitization, and systemic toxicity testing as stipulated under Part III B above. See ODE Guidance Memoranda G95-1, May 1, 1995.*]

V. STATEMENT OF SUBSTANTIAL EQUIVALENCE

Indicate whether the condom has the same intended use and technological characteristics as the predicate condom. Summarize the similarities and differences of the features and technological characteristics of the condom in comparison to the predicate condom.

VI. LABELS, LABELING AND ADVERTISEMENTS

Provide proposed labels, labeling and advertisements sufficient to describe the device, its intended use, and the directions for use. (21 CFR 807.87(e)) For overall labeling guidance, manufacturers are encouraged to consult with FDA's manual "Labeling: Regulatory Requirements for Medical Devices," (HHS Publication FDA 89-4203). (Also see Title 21 CFR §801, §801.435 and §801.437.) Labeling for latex condoms should include but not be limited to the following:

A. Statement of Identity and Intended Use

1. The principal display panel as defined in 21 CFR 801.60 and primary package (individual condom packet) should identify the device as a male **LATEX** condom.

2. The principal display panel and primary package should identify the intended use for male condoms, i.e., contraception.

3. The principal display panel, and primary package (individual condom packet) should also include the following statement:

   If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.

The following expanded statement should be added to the package insert, directions for use:

If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

4. Special labeling is required for condoms lubricated with a spermicidal lubricant. The principal display panel, primary package and any package insert must prominently and conspicuously bear a specific contraceptive effectiveness cautionary provision:

   This product combines a latex condom and a spermicidal lubricant. The spermicide, nonoxynol-9, reduces the number of active sperm, thereby decreasing the risk of pregnancy if some semen spills or seeps outside the condom. However, the extent of decreased risk has not been established. This condom should not be used as a substitute for the combined use of a vaginal spermicide and a condom.

B. The package insert for latex condoms should contain a contraceptive effectiveness table with pregnancy rates for all drug and device contraceptives. This information will enable contraceptive users to compare their contraceptive to alternatives and make appropriate choices. FDA has developed such a table entitled "Pregnancy Rates for Birth Control Methods," that can be used for this purpose. This table is the result of an intra-agency effort that included focus studies funded by FDAs Office of Womens Health. Data for this table comes from Contraceptive Technology, 17th ed., Hatcher et al., and will be updated periodically as new data becomes available.

   See ODE guidance entitled "Uniform Contraceptive Labeling: Guidance To Industry."

C. The Center has issued specific guidance that established the intended use and suggested directions for use for male latex condoms. This guidance provides acceptable and appropriate labeling. The following are suggested precautions and directions for use:

   Precautions

   - **Use a new condom every time you have sexual intercourse or other acts between partners that involve contact with the penis.**
   - **Do Not Reuse Condoms.**
   - **Store condoms in a cool, dry place.**
   - **If the rubber material is sticky or brittle or obviously damaged, do not use it.**
   - **If a lubricant is wanted, use water-based lubricants such as [<u>name of product</u>]. *DO NOT USE OIL-BASED LUBRICANTS*, such as those made with petroleum jelly (e.g., Vaseline®), mineral oil, vegetable oil, or cold cream, as these may damage the condom.**

Directions for Use

- **Put the condom on after the penis is fully erect and *before* intimate contact. Lesions, pre-ejaculate secretions, semen, vaginal secretions, saliva, urine, and**

feces can all transmit disease organisms.

- **Place the condom on the head of the penis and unroll or pull it all the way to the base.**

- **Leave an empty space at the end of the condom to collect semen. Remove any air remaining in the tip of the condom by gently pressing the air out toward the base of the penis.**

- **After ejaculation and while the penis is still erect, hold onto the rim of the condom so that the condom does not slip off as the penis is carefully withdrawn.**

D. The retail and primary package (individual condom packet) must include an expiration date. (See 21 CFR §801.435, User labeling for latex condom, effective March 25, 1998.)

E. On September 30, 1997, FDA published a Final Rule (62 FR 51021-51030, 1997), codified at 21 CFR 801.437, which will require all medical device products composed of or containing, natural rubber latex and which contact humans, such as latex condoms, to bear the following statement in bold print on the device labeling, in conformance with Section 502(c) of the Act:

CAUTION: THIS PRODUCT CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS

This statement must appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container or wrapper. This final rule has an effective date of September 30, 1998. This labeling requirement is considered necessary because devices composed of, or containing, natural rubber latex, pose a significant health risk to some individuals. (See also, FDA's March 29, 1991, FDA Medical Alert, Allergic Reactions to Latex Containing Medical Devices. MDA91-1.)

VII. INDICATIONS FOR USE STATEMENT

510(k) Number: (if known)

Device Name: [*Brand Name*] Male Natural Rubber Latex Condom

Indications For Use: The [*Brand Name*] condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

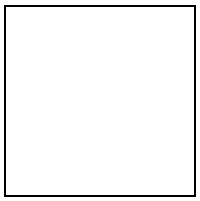
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR §801.109)

Tab 1 - Device Description

Provide a diagram (or diagrams) of the subject latex condom. The diagram should show key dimensions, as well as relevant contours.



Provide all relevant product specifications that adequately characterize the condom. Given below is an example of how this information should be given.

Typical (Average) Product Characteristics

- Nominal length (mm)
- Nominal width (mm)
- Nominal thickness (mm)
- Air burst test pressure
- Air burst test volume
- Materials of the primary package (individual condom packet)
- Lubricant system (include viscosity)

Tab 2 - Compounded Latex Formulation

Provide a complete summary of the compounded latex formulation and other materials used in the manufacture of the condom. Given below is an example to illustrate how this information should be given.

TABLE 1 - Compounded Latex Formulation Summary

Generic Name & Chemical Composition	CAS No	Percentage Range PPH $_{LATEX}$	Function
Natural Rubber Latex (cis-1,4-polyisoprene)		100.00	
Diisopropyl xanthogen polysulfide		--	Vulcanizing agent (cross-linking)
Sulfur		--	Vulcanizing agent (cross-linking)
Zinc Oxide		--	Activator
Zinc-N-diethyl-dithio-carbomate		--	Accelerator
Zinc-N-dibutyl-dithio-carbomate		--	Accelerator
Potassium Hydroxide		--	Stabilizing agent
Sodium lauryl sulfate		--	Emulsifier
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt		--	Emulsifier
Ammonia			Preservative
Formaldehyde			Preservative
		--	Antioxidant
		--	Anti-ozonants

TABLE 2 - Compounded Formulation Condom Additives

Generic Name & Chemical Composition	Supplier	CAS No.	Amount (mg)
Dusting Agents			
U.S.P. Corn Starch			
Lubricants			
Silicone (polydimethylsiloxane)			
Nonoxynol-9			

TABLE 3 - Condom Composition Summary - Colors

Color	Pigment	C.I. No.	CAS Reg. No.	21 CFR Citation	Amount PPH $_{LATEX}$
Red	C.I. Pigment Red 48:2 Permanent Carmine	C.I.#12490		73.100	
Blue	C.I. Pigment Blue 15:2/Copper Phthalocyanine Blue	C.I. #74160	CAS Reg No.147-14-8	178.3297(e)	
Green	C.I. Pigment Green 7/Polychloro Copper Phthalocyanine Green	C.I. #74260	CAS Reg No.1328-53-6	178.3297(e)	
Yellow	C.I. Pigment Yellow 74 Azo Yellow	C.I. #11741	CAS Reg No.6358-31-2	177.2600	