This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer 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. This guidance will be updated in the next revision to include the standard elements of GGP's.

5/10/95

510(k) Guidance Document for General Surgical Electrosurgical Devices

I. Introductory Information

A. Scope

This document establishes the 510(k) review requirements for general surgical electrosurgical devices including electrosurgical generators, monopolar and bipolar open, endoscopic and laparoscopic devices and their accessories. This document is not for electrocautery devices.

B. Purpose

This guidance is intended to:

1. assist manufacturers, distributors, or importers in organizing premarket notifications for electrosurgical devices and accessories;

2. achieve consistency in meeting of requirements and in the presentation of information; and

3. guide FDA review staff in conducting and documenting the review of electrosurgical device premarket notifications.

C. Definitions

1. Electrosurgical device - a device that effects tissues via the use of a high frequency electrical current waveform passing into the tissue.

2. Electrocautery device - a DC current device that effects tissues with intense heat generated by resistance in a metal tip or wire loop.

3. Electrode Probe - an electrosurgical assembly that contains a handle or "handpiece".

4. Electrode - the small metal piece that fits into a chuck at the distal end of a probe.

5. Intended Use - a statement of all conditions, purposes, or uses for which the device is intended, including conditions, purposes, or uses for which it is recommended, prescribed, or suggested in its oral, written, printed or graphic advertising or uses for which the device is commonly used.

6. ESU - Electrosurgical Unit generator produces the high frequency current waveform that is delivered to tissues via the connecting cable, probe and electrode.

D. General Principles Regarding Presentation of Data

1. Editorial Considerations: The 510(k) should be carefully edited, as well as scientifically reviewed before it is submitted to FDA. It should be proofread to assure that all pages/sections are included and are properly indicated, consecutive, distinctly copied, and legible.

2. Abbreviations: Standard abbreviations acceptable to a peer reviewed journal should be used wherever possible. All other abbreviations should be identified at the beginning of each section in which they are used or in footnotes to tables and graphs.

3. Data Availability: This document outlines typical circumstances of data review. It is not possible to anticipate all situations that may require FDA review. Thus, those submitting applications should be aware that they may be asked to submit additional data, to present data in another format or to provide more detailed explanations of the information submitted, if required to establish equivalence.

   Applicants should keep data used for the 510(k) submission on file in a controlled and well organized format. This will allow the applicant to expeditiously supply FDA with additional information or analysis if required. Errors in data that are identified by the applicant after submission to FDA should be brought to FDA's attention immediately.

4. Tables and Graphs: Well-constructed tables are fundamental to the reporting and evaluation of data. All tables should be clearly identified and captioned with symbols keyed to a footnote or accessible reference page that adequately indicates the nature of the data. (See Attachment 1)

   Graphs should supplement, not replace, data tables. They should be of a high quality.

5. Published Literature: Published methods or data referenced in study reports should be appended to the study report. Reprints of other referenced published reports or data should be appended to the section in which they are referenced. All referenced reports and data should be summarized including an explanation how it relates to the current submission. Reference citations should be complete (e.g., title, author, volume, year).

6. Protocols and Data Analysis:

Test reports must include the protocol (objectives), precise description of materials, experimental methods, controls, observations, statistical methods and analyses, conclusions, and comments. Do not submit raw data. Additional specific directions on protocols are included in sections that follow.

7. Reference to Submitted Data:

The applicant may reference any information previously submitted to FDA in support of the 510(k). If they did not originally submit the referenced data, then they must provide, or have the submitter provide to FDA, a letter of authorization. Often, if the data are not extensive, resubmitting data in the 510(k) will facilitate the review of the document.

E. Document Availability

The following documents referenced in this guidance are available from DSMA [(800) 638-2041]:

- ISO 10993 Biological Evalutaiton of Medical and Dental Materials and Devices
- ODE Blue Book Memorandum #K90-1: 510(k) Sterility Review Guidance
- Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(K) Review (revised 8-29-91)
- ODE Blue Book Memorandum #G91-1: Device Labeling Guidance

II. Content and Organization of Information in a 510(k)

A. Cover Letter

The submission shall have a cover letter providing the following information described in 21 CFR 807.87 (Information required in a premarket notification submission):

1. The device's trade or proprietary name.

2. The device's common or usual name (e.g., electrosurgical probe, electrosurgical electrode, electrosurgical handpiece, etc.).

3. The device's classification name is electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400).

4. The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

5. Electrosurgical devices and their accessories have been put in class II under section 513 of the act, and its appropriate panel is 79, General and Plastic Surgery Devices.

6. A statement explaining the purpose of the submission (e.g., new device, significant modification of device previously found equivalent, new intended use, new material, or different manufacturing process, etc.). Refer to §807.87(g) for additional requirements. The change may require some or all of the information needed for a new device

7. A brief statement indicating how the device is similar to and/or different from other products of comparable type in commercial distribution.

B. Labels and Labeling

1. The submission should contain proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for use. Labels include the information affixed directly to the device and its packaging. Labeling also includes the users manual, service manual, home use labeling, and any other information that accompanies the device.

2. The labeling must meet the requirements of 21 CFR Part 801 as it relates to a determination of intended use. ODE will therefore concentrate on the following:

   Subpart A, Sections 801.4 and 801.5, related to intended uses and adequate directions for use.

   Subpart B, Sections 801.109 and 801.116, related to prescription devices and commonly known directions.

   Other portions are deferred for review by ODE staff to CDRH/OC Promotion and Advertising Policy Staff.

3. The labeling should meet Blue Book Guidance G91-1, Device Labeling Guidance.

4. The following information should be included in the labeling for electrosurgical devices:

   a. If the device is monopolar, a statement must be provided to keep the voltage/power as low as possible to achieve the desired end effect. (This is needed due to the potential for capacitive coupling and inadvertent burning at high voltages.)

   b. If a manufacturer offers a laser channel with their device, the manufacturer must warn the user not to activate both laser and ESU simultaneously. In addition, the manufacturer must state that the electrode tip be pulled back from the laser fiber when the laser is in use so that the laser will not inadvertently be focused on the electrosurgical tip or shaft insulation. Vice versa, the laser fiber must be pulled back when the electrode is being used to keep arcing from occurring, especially if the laser fiber has a metal tip attached. Also, the user must be referred to the laser system's instruction manual for information on the proper use of the laser.

   c. With a suction/irrigation feature, labeling should caution the user that activating the electrosurgical unit simultaneously with the aspiration /irrigation mode may alter the path of the electrical energy away from target tissues.

   d. If the device is laparoscopic and/or Argon beam enhanced, a gas embolism warning is required.

e. If the device is laparoscopic monopolar, a caution should be provided that states, activation of an electrosurgical device when not in contact with target tissue or in position to deliver energy to target tissue (fulguration) may cause capacitive coupling.

Each of the above items of information included in your submission should be highlighted to facilitate the review.

C. Standards

The following are commonly referenced standards for electrosurgical devices:

1. ANSI/AAMI American National Standard for Electrosurgical Devices HF-18/1993.

2. International Electrotechnical Commission Standard for Electrosurgical Devices, IEC 601-2-2.

The applicant may certify that their device meets the stated standards and maintain documentation of testing showing that the device does meet that standard. Certification to meeting a specific standard may reduce the data requirements for the 510(k) submission.

If a manufacturer wishes to deviate from the test requirements identified in one of the above standards, they need to provide their test protocol and test results to demonstrate that their device design is at least as safe as the cited predicate device.

D. Device Description

The applicant must submit a complete description of the device.

1. Provide a description of the device in sufficient detail to facilitate the evaluation of the nature and operation of the device (e.g., photographs, block diagram, detailed drawing, blowup, engineering drawings, or waveform pictures may be needed). Labeling may include sufficient representations of the device.

2. Provide a clear description of the intended use(s) of the device. For example, the device is for single use only, disposable, or reusable, cutting and coagulating soft tissues, fulguration, Argon beam enhanced coagulation, etc.. Pay particular attention to the distinction between electrocautery and electrosurgery (see definitions). Devices labeled for specific procedures or treatment of specific disease conditions may require additional clinical information not outlined in this document.

3. Provide complete specifications for the device including the physical (all dimensions), mechanical (strength of joints, other design features), and **electrical** (maximum energies used, powers attained, complete output waveform(s) characterization for each mode of operation) parameters.

4. Provide a complete listing of all materials used in fabricating the device. In some cases (with adequate explanation) the list of materials may be limited to major components such as direct or indirect body contacting materials or major components.

E. Descriptive Comparison to a Legally Marketed Device

Identify a legally marketed device to which substantial equivalence is claimed. If possible, identify the 510(k) numbers. More than one device can be listed, but the device(s) chosen should be as close in intended use and technology to the new device as possible. Provide the information noted below to show how the new device is similar to and different from the legally marketed device. Side by side comparisons, whenever possible are desirable. Attachment I is an example comparison table. This information may be identical to that provided under Part C and the applicant may wish to combine some or all of Part C and D information. Indicate how the differences may affect safety and effectiveness.

1. Provide labeling (labels, instructions for use, promotional material) for the legally marketed device(s) to which substantial equivalence is claimed. To facilitate comparison, also include clear photographs, or other representations of the legally marketed device(s), unless the labeling has ample information.

2. Compare and contrast the intended use for the new device to the predicate.

3. Compare and contrast all materials used to fabricate the specified or major components. The precise materials of the new device, and if possible, the predicate should be identified to the extent possible. Particular attention should be given to insulation materials and their specifications.

4. Compare and contrast the operational principles, including mode(s) of action and output characteristics.

5. Compare and contrast physical, mechanical, **electrical**, and etc. specifications.

F. Performance Data Supporting Substantial Equivalence

In certain cases descriptive data alone will not be sufficient to establish equivalence. Comparisons of performance of the new device to a legally marketed device may be necessary. Data may be required to substantiate label claims or specifications.

Provide the protocols and results of specified tests needed to establish equivalence. If the stated test is a standard method that specifically addresses the performance criterion, then the applicant may reference the method and certify that the device will meet the criterion (see standards). Data need not be submitted in this instance.

The studies should be well-designed to meet the stated objectives. This will include rigorous attention to: statistical elements (hypotheses, test statistic, analyses, sample size and sampling, power, etc.), inclusion/exclusion criteria, controls, minimization of bias, test parameters (endpoints), follow up, evaluation criteria, etc. Some of the above points may overlap. Ample reference material exists on study design and methods upon which the applicant may rely if the method is not specified in the guidance (e.g., biocompatibility).

The following are the types of data required to be provided, if needed, to substantiate the device substantial equivalence claim:

1. <u>Bench/In Vitro Data</u>

   a. Engineering

      As a minimum the device should meet ANSI/AAMI HF-18/1993. Particular attention should be paid to insulation materials. For laparoscopic/endoscopic devices, include results from a test for capacitive coupling resistance between your device and a conductive material cannula/trocar device under simulated normal use conditions.

b. Biological (biocompatibility see item 2a below)

2. Animal Data

a. Biocompatibility: certify that the identical materials have been used in other legally marketed devices used under the same use conditions, or provide documentation attesting to the biocompatibility of the component materials in the finished product according to the 1987 Tripartite Guidance and/or ISO 194 draft standards. The delayed sensitization assay is the only test accepted for long term sensitization data.

b. Animal test data for the intended use may be required if the descriptive and bench test data are insufficient to establish the substantial equivalence claim.

3. Clinical Data

Clinical data for the intended use may be required if the descriptive, bench test, and animal data are insufficient to establish the substantial equivalence claim. Typically, clinical data may be sought for a "new" intended use or a "new" indication for use, i.e. not previously cleared by FDA or on the US market prior to May 28, 1976.

G. Sterilization Information
See Attachment 2

H. Software Validation (if applicable)

The [**your device name**] must meet the [enter **minor, moderate, major**] level of concern as outlined on pages 17 - 25 of the Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(K) Review (revised 8-29-91). This document describes the required documentation and it is available from the FDA Division of Small Manufacturers Assistance (DSMA). Phone (800) 638-2041.

For minor concern devices: The applicant may submit a certification that they will meet all the requirements outlined in the above guidance.

For moderate and major concern devices: The applicant must submit the information indicated in the guidance. The FDA considers computer controlled electrosurgical devices to be in the moderate concern level. However, a higher level of concern may be justified if the device's features and/or intended use meet the major concern level definition in the above guidance.

I. SMDA 1990 Information

1. Summary or Statement of Safety and Effectiveness

All persons submitting a 510(k) must include either a summary of safety and effectiveness information in the 510(k) upon which an equivalence determination could be based **OR** a statement that safety and effectiveness information will be provided. As noted in the Federal Register Vol. 59, No. 239, 12-14-94, p. 64291, §807.93, the 510(k) statement shall read as follows: 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.

[*Signature*]

_____

[*Typed Name*]

_____

[*Dated*]

_____

[*Premarket Notification (510(k)) Number*]

If the summary option is selected, it should be included on a separate page and identified as the 510(k) Summary of Safety and Effectiveness for [**your device name**]. The 510(k) Summary shall comply with 21 CFR §807.92 as amended in the Final Rule published in the Federal Register Vol. 59, No. 239, 12-14-94, p. 64295.

I. SMDA 1990 Information (Continued)

2. Premarket Notification Truthful and Accurate Statement

As Required By 21 CFR 807.87(j), all 510(k) submitters must provide a statement as follows:

I certify that, in my capacity as [*The Position Held In Company*] of [*Company Name*], I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

[*Signature*]*

_____

[Typed Name and Title]

_____

[Company] [Date]

_____

[*Premarket Notification (510(k)) Number*]

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

Attachment 1
EXAMPLE COMPARISON TABLE

Feature	**New Device**	**Predicate**
Intended Use for Device		
Design Specifications		
Output Energy		
Output Waveform(s)		
Delivery System Configuration Length(s) Diameter(s)		
Tip configuration(s)		
Bipolar / Monopolar		
Bench Testing		
Performance Test Results:		
Meets ANSI/AAMI HF-18		
Meets IEC 601-2-2		
Material Composition		
Biocompatibility Tests		
Sterilization Method(s)		

ATTACHMENT 2
STERILITY INFORMATION

For a device sold sterile, provide the following information as detailed in the ODE Blue Book Memorandum #K90-1.

1. Sterilization method that will be used.

2. A description of the method that will be used to validate the sterilization cycle, but not the validation data itself. Reference to a standard method (e.g., AAMI Radiation Standard) usually is sufficient.

3. The sterility assurance level (SAL) for the device which the firm intends to meet. An SAL of 10^{-6} is required for devices which contact normally sterile areas of the body.

4. A description of the packaging to maintain the device's sterility (this is not to include packaging integrity testing data).

5. If sterilization involves EtO, the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol which remain on the device should be consistent with **FR, Vol. 43, No. 122-Friday, June 23, 1978** notice on EtO residuals. Typically, the EtO residual levels for contacting mucosa is sufficiently low for electrosurgical devices (250, 250, & 5000ppm respectively).

6. Whether the product is "pyrogen free" and an identification of the method used to make that determination.

7. The radiation dose, if radiation sterilization will be used, and if it has been determined. Otherwise, amend the 510(k) file at FDA when the dose has been determined.

8. Reusable devices must include a recommended sterilization method with applicable cycle parameters. Please see Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, March 1995 draft available from DSMA at (800) 638-2041.

ATTACHMENT 3
KIT INFORMATION

The applicant must provide the following for a kit. i.e., a package consisting of at least one medical device and additional devices, drugs, or biologics as other components.

1. Include a complete and specific listing of all components of the kit(s).

2. Certifications:

   (a) I certify that the medical device components of my kit listed on page(s) [SUBMITTER PROVIDE PAGE NUMBERS] are either (1) legally marketed preamendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulations and the limitations of exemptions from Section 510(k) of the act (e.g., 21 CFR 862.9), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is intended (i.e., not claiming or causing a new use for the component(s)).

   (b) I further certify that I purchase the device components in finished form, i.e., they are packaged, labeled, etc., consistent with their preamendments, exemption, or premarket notification criteria and status. All purchased drug or biologic components are also packaged and labeled consistent with their approval or licensing.

   If you cannot make certification statement (a) for each device component of your kit, you must itemize the components without preamendments, exemption, or premarket notification status. You must also supply adequate information, which may be the same information needed for a separate 510(k) for each component, so that FDA can evaluate the equivalence of these components of your kit.

   If you cannot make certification statement (b), and you purchase the components, then identify the components purchased in unfinished form, e.g., packaged in bulk (not final packaged and labeled in separate units).

3. Clearly identify in the list of kit components any that are drugs and biologics. For example, state next to the item that it is a drug or a biologic.

4. Describe how the kit is assembled and processed into finished form for purchase (e.g., the components are taken out of the finished product or bulk packaging, component X is individually sterilized, all the components are then placed on a tray, the kit is wrapped, but not sterilized prior to shipment).

   If there is any repackaging or reprocessing of a separate component, then you must provide details on the repackaging or processing and an analysis of the effect on the component. This may require testing. For example, for (re)sterilized devices conduct a validation study and provide data in accordance with the ODE Sterility Blue Book Memorandum. The processing of the final kit is also important. You must evaluate whether the final processing for the kit as a whole affects the safety or effectiveness of any of the kit components.

5. The 510(k) should include all labels and labeling for the kit. A kit label alone may suffice for all components only if the label consolidates the required information typically found in labeling for each individual kit component when sold separately in final form. A component may require specific labeling, such as a package insert, when adequate directions for use (precautions, warnings, etc.) are required. It is important to examine the labeling for the individual components sold separately versus the labeling provided for the kit. Verify that the labeling is adequate or enclose additional labeling in the kit, as needed.

6. The items above identify labeling and processing issues which may affect the regulatory status, or safety and effectiveness of the kit. If you are aware of any other factor which may impact upon the status of your kit, then please bring it to our attention so that we may consider it in our evaluation.

ATTACHMENT 4
REVIEW CHECKLIST

The section block is checked if the information is lacking.

The applicable information included below, except that with an asterisk, must be supplied in some form before the review can begin. The information may be in another section than that indicated. The checklist can also indicate the required information for an amendment.

		CHECK IF NEEDED
A.	Cover letter	_____
1.	Trade or proprietary name	_____
2.*	Common or usual name	_____
3.*	Classification name	_____
4.*	Registration #	_____
5.*	Class and panel #	_____
6.	Purpose of submission	_____
7.	Equivalence statement	_____
B.	Labels and Labeling	_____
•	labels	_____
•	labeling	_____
•*	promotional literature	_____
C.	Standards Met	_____
D.	Device Design	_____
1.	Description	_____
2.	Intended use	_____
3.	Specifications	_____
4.	Materials	_____

E. Comparison to Legally Marketed Device _____

1. Labeling Provided _____
2. Intended use _____
3. Materials _____
4. Mode of action _____
5. Specifications _____

F. Tests Supporting Labeling Statements, Performance and Safety Specifications _____

1. Bench/in vitro _____
2. Animal _____
3. Clinical _____

G. Sterilization, Attachment 2 _____

H. Software Validation _____

I. SMDA 1990 Information _____

1. Statement/Summary _____
2. Class III information _____
3. Truthful and Accurate Statement _____

* Denotes information that may not be essential for FDA to complete their review.