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.

DRAFT GUIDANCE FOR THE CONTENT OF PREMARKET NOTIFICATIONS

FOR ENDOSCOPES USED IN GASTROENTEROLOGY AND UROLOGY

Draft: 3/17/95

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Introduction.

The purpose of this guidance document is to identify the type of information that needs to be provided in a premarket notification (510(k)) to support a determination of substantial equivalence for endoscopes intended for use in gastroenterology and urology.

Endoscopes and accessories are described in the Food and Drug Administration (FDA) regulation, 21 CFR 876.1500(a), as "device(s) used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices." Due to the diversity in their design and intended use, endoscopic accessories (such as biopsy forceps, stone baskets, snares, light sources, etc.), are not specifically addressed in this guidance document. Separate guidance documents are available for a number of endoscopic accessories. This guidance also does not address general surgical laparoscopes; for information on these devices, contact the General Surgery Devices Branch at (301) 594-1307.

General guidance concerning the information required to be in a 510(k) is available in the draft guidance entitled, "Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices (DRAERD) Draft Guidance for the Content of Premarket Notifications." Additional guidance is outlined in the Center for Devices and Radiological Health's, "Premarket Submission Cover Sheet," the use of which is encouraged. Copies of these two documents and the aforementioned documents on endoscopic accessories may be obtained from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597.

For more information contact DSMA or the:

Urology and Lithotripsy Devices Branch
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
(301) 594-2194.

I. Device Identification.

A. Device Name.

Provide both the trade or proprietary name of the device proposed for marketing, as well as the common or usual name for the particular type of endoscope (e.g.,

choledochoscope or cystoscope).

B. Predicate Device Name.

Identify the legally marketed device(s) to which the new device will be compared. Be as specific as possible, e.g., proprietary and common name, manufacturer, model number, 510(k) reference number, pre-Amendments status, etc.

II. Classification and Product Code.

The Code of Federal Regulations (CFR) number, class, and product code of the endoscope should be provided. All gastroenterological and urological endoscopes are listed under 21 CFR 876.1500, Endoscopes and Accessories, and are Class II Devices. The following is a list of product codes for various subcategories of endoscopes:

Device	Product Code
· Colonoscope	FDF
· Cystoscope	FAJ
· Cystourethroscope	FBO
· Electrical Rigid Sigmoidoscope	FAN
· Endoscope and/or Accessories	KOG
· Enteroscope	FDA
· Esophagogastroduodenoscope	FDT
· Flexible Sigmoidoscope	FAM
· Flexible or Rigid Choledochoscope	FBN
· Flexible Endoscope	GCQ
· Nephroscope	FGA
· Non-Powered Anoscope	FER
· Resectoscope	FJL
· Rigid Endoscope	GCM
· Ureteroscope	FGB
· Urethroscope	FGC

III. Section 514 Special Controls.

Special Controls under Section 514 of the Act have not been developed for these devices. Reference is made in later sections of this document to voluntary industry standards.

IV. Device Description.

This section identifies the information necessary to evaluate the endoscope's technological characteristics. Additional information may be required depending on the individual design and function of the device. **In order to permit an equivalence determination, all of the device characteristics and performance data presented in the**

premarket notification should be compared to a legally marketed device whenever possible.

A. Intended Use.

The 510(k) must provide a clear statement of the device's intended use, including the indications for use (see Section V.A.). Acceptable generic intended use statements for the above listed product codes are given below.

FDF — Colonoscope - used to examine the colon, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FAJ — Cystoscope - used to examine the urinary tract, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FBO — Cystourethroscope - used to examine the bladder, urethra and distal ureter, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FAN — Electrical Rigid Sigmoidoscope - used to examine the rectum and distal sigmoid, and, using additional accessories, to perform various diagnostic and therapeutic procedures

KOG — Endoscope - used to examine body cavities, hollow organs and canals, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FDA — Enteroscope - used to examine the esophagus, stomach and small intestine, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FDT — Esophagogastroduodenoscope - used to examine the esophagus, stomach and duodenum, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FAM — Flexible Sigmoidoscope - used to examine the lower bowel tract, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FBN Flexible or Rigid Choledochoscope - used to examine the bile ducts, and, using additional accessories, to perform various diagnostic and therapeutic procedures

GCQ Flexible Endoscope - an endoscope which is designed with a flexible insertion tube which is used to examine body cavities, hollow organs and canals, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FGA Nephroscope - used percutaneously to examine the interior of the kidney, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FER Non-Powered Anoscope - used to examine the anal sphincter and the anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FJL Resectoscope - used to perform various diagnostic and therapeutic procedures in the transurethral resection of tissue

GCM Rigid Endoscope - an endoscope which is designed with a rigid insertion tube which is used to examine body cavities, hollow organs and canals, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FGB Ureteroscope - used to examine the ureter, and, using additional accessories, to perform various diagnostic and therapeutic procedures

FGC Urethroscope - used to examine the urethra, and, using additional accessories, to perform various diagnostic and therapeutic procedures

B. Diagrams, Dimensions, and Materials.

Provide diagrams of the endoscope, with all key dimensions and component materials well marked. Clearly identify all working channels and the working length of the device. Multiple diagrams may be necessary to show adequate detail. These should include cross-sectional diagrams at the distal and

proximal ends of the instrument as well as at the midpoint. These diagrams may be labeled in greater detail or additional diagrams may be provided to further clarify the information requested in the subsequent sections.

A table listing all patient contacting materials should be provided. The results of biocompatibility testing performed on these materials, or a certification stating that the material formulation used is identical to that used in a legally marketed device with a similar intended use, is also needed. Endoscopes are considered to be short-term mucosal contacting, externally communicating devices and testing should include, but is not limited to, mucosal irritation, sensitization, cytotoxicity, acute systemic toxicity, and short-term implantation. For additional information on biocompatibility, please refer to the "Tripartite Biocompatibility Guidance for Medical Devices" (Sept. 1986). A copy of this guidance may be obtained from DSMA.

C. Optical Performance Characteristics.

1. Specifications

a) Specific Optical Performance Characteristics

Provide the following performance specifications, depending upon the specific design of the scope optics:

i) Rigid Rod-Lens Systems

1) Lens diameters (mm)
2) Endoscope length (mm) and diameter (mm)

Endoscope length should include working length and total length. Working length and diameter should correspond to the intended clinical purpose.

ii) Fiberoptic Imaging Systems

1) Total number of fibers
2) Fibers per square millimeter
3) Size of fiber core (mm)
4) Area of active fiber per square millimeter
5) Identify predicate device that also utilizes this fiber, if applicable

iii) Electronic Video Imaging Systems

1) Total number of pixels
2) Pixels per square millimeter
3) Size of pixel (nm)
4) Active area of CCD chip (mm)
5) Type of CCD chip (e.g., color or monochrome)

b) General Optical Performance Characteristics

Provide the following performance specifications for the new endoscope, regardless of design:

i) Field of View (stated in degrees)

Due to their use in an aqueous environment, field of view should be reported in both air and water for urological endoscopes and choledochoscopes; air can be used for all other gastroenterological endoscopes.

ii) Direction of View (stated from the center of axis)

1) The direction of view for rigid scopes should be stated in degrees and direction (i.e., 0◦/forward)

2) The direction of view for flexible scopes should be stated in degrees of tip angulation

iii) Depth of Field/Working Distance (stated in mm)

Provide the depth of field or working distance (mm) and the F# of the objective lens at optimum working distance. Clearly define the optimum working distance.

iv) Image Quality

1) Resolution (stated in lines/mm)

There are several bar patterns available to use as an acceptable method of assessment of device resolution. These bar patterns include: (1) USAF bar pattern, (2) NBS 1010A Microcopy Test Chart, or (3) ANSI/ISO Test Chart #2. The test setup should have the bar pattern on axis and should optimize the magnification and illumination.

At a minimum, the endoscope should be able to resolve at least 5 lines/mm (bars spaced at 200μ). The highest level of resolution (i.e., the finest pattern in which the scope can distinguish the bars) should be stated.

A justification along with the identification of a legally marketed predicate with an equivalent resolution value should be provided for any device with a resolution below 5 lines/mm.

2) Distortion Characteristics

Provide information on the distortion introduced by the fiberoptics and objective lens combination. As an example, this could be provided by imaging a piece of graph paper and providing a comparison of the paper and the photographed image of the graph paper. If the distortion is corrected by signal processing, provide the resulting, corrected image of the graph paper.

3) Magnification

State the magnification of the objective lens, eyepiece, and relay lens.

4) Focal length (stated in mm)

State the standard focal length and any potential for changing the focal length (e.g., zoom feature, eyepiece

magnification, etc.).

2. Environmental Effects on Optical Performance

If solarization or tinting effects, aging effects, or effects due to irradiation (either through light or radiation) produce a change in the fiber transmission, show that this does not impair its clinical use.

D. Mechanics.

The information provided for system mechanics should address changes that may occur as a result of sterilization and/or any other reprocessing expected during the intended use of the device. At a minimum, the following information on the mechanical aspects of the endoscope should be included:

1. Bending mechanism and its controls (Flexible Endoscopes)

The angular range of the scope should be reported. Testing that shows that the endoscope can be repeatedly curved throughout the specified range without damage to any component should be provided. Specific information on any fiber damage noted during this testing should be described.

If the tip of the device is intended to be controlled separately from the main shaft, additional testing should be performed. This testing should show that the angular range claimed can be achieved, that any safety release on the locking mechanism operates efficiently, and that the controls are sufficiently sensitive to warn the operator of obstructions to the bending force.

2. Any other mechanical systems or controls

Working channels should be designed to withstand the forces acting upon them during the expected lifetime of the device. If a working channel will be subjected to mechanical accessories, the ability of the inside wall to resist scratching and gouging should be assessed.

E. Electrical Safety.

The following minimum electrical safety testing should be performed for all endoscopes. If applicable, compliance with industry standards (IEC 601-1, UL 544, and IEC 601-2-18) should be cited.

1. Test of electrical isolation from both the patient and the physician

2. Leakage current measurement

F. Thermal Safety.

Data demonstrating that the device does not present a thermal hazard to the patient during a typical exposure time should be presented. As an example, this could be provided by plotting the temperature versus time for several key locations (including the tip) on the outside of the endoscope.

G. Electromagnetic Compatibility.

Either certification that the device complies with acceptable standards for Immunity and Emissions (i.e., CISPR 11, IEC 601-1-2), test results which guarantee a similar level of protection, or a justification of why this information is unnecessary (e.g., due to device design or working conditions) should be provided.

H. Reprocessing.

1. Background

Gastrointestinal (GI) endoscopes (trans-oral and trans-rectal) and urological (GU) endoscopes (trans-urethral) are considered semi-critical devices by the Centers for Disease Control (CDC) and therefore require, at a minimum, high level disinfection. Percutaneous endoscopes such as choledochoscopes and nephroscopes which contact or enter sterile tissue are considered critical devices and, therefore, require sterilization before use.

2. Required Information

Provide detailed instructions for reprocessing (cleaning and disinfecting/sterilizing) the device, including instructions necessary for any assembly/disassembly. Also, include a warning

that the device should be thoroughly cleaned and disinfected/sterilized according to validated infection control procedures prior to use/reuse.

a. The cleaning instructions should describe careful, manual cleaning and rinsing of both the endoscope's exterior surface and interior channels using a brush and detergent/ enzymatic solution to dissolve and loosen proteinaceous materials immediately after use. (Flexible endoscopes require cleaning of the suction/biopsy channel in the insertion tube, umbilical cord and control head while rigid instruments require careful cleaning of the external surface and any internal channels.) The cleaning instructions should identify compatible cleaning solutions by generic names (e.g., enzymatic cleaning solutions, protein binding agents, etc.) and any areas of the device that are particularly difficult to clean, as well as any specified methods and necessary accessories (e.g., brushes).

b. The rinsing instructions should include purging of all internal channels (if applicable) alternately with air and water.

c. Leak testing before immersion of the control head of flexible endoscopes should be described. This may be either a dry test using a pressure gauge or a wet test which relies on evidence of air bubbles when the inflated portion is submerged in water.

d. The high level disinfectants used to disinfect semi-critical devices must be identified and cleared by FDA. General reference to a class of germicides, e.g., 2% glutaraldehyde, is currently acceptable. Instructions should recommend that the entire endoscope be exposed to the liquid chemical germicide according to the labeling of the germicide (appropriate time and temperature). High level disinfection may be manual or automated, and, if automated, instructions must identify suitable adapters for all interior channels of the endoscope.

e. Thorough post process drying instructions should be recommended, as needed, in order to minimize recontamination before reuse.

Instructions should include a step where air is forced through all channels following either manual or automated reprocessing to remove residual rinse water. A 70% alcohol flush should be used as a drying agent followed by forced air drying at the end of each day for disinfected flexible instruments.

f. Specify at least one validated method for disinfection or sterilization, and identify the specific parameters (e.g. cycle parameters, aeration, specific liquid chemical germicide, loading of sterilizer, etc.) which should be used. If the labeling lists a generic type of sterilization or disinfection process with no specifics on cycle parameters, then the applicant must validate all forms of the listed generic process, e.g., "steam sterilization."

g. Provide information to help the user identify any circumstances or conditions when the device may be adversely affected by reprocessing. This information should address the material compatibility with the immersion fluid.

h. Provide a certification regarding validation of the reprocessing instructions signed by the applicant, its agent, or other legally responsible individual.

For important additional information on reprocessing, please refer to the draft "Labeling Reusable Medical Devices Reprocessing In Health Care Facilities: FDA Reviewer Guidance" (March 1995). A copy of this guidance may be obtained from DSMA.

V. Labeling.

Proposed labels, labeling, and any promotional information sufficient to describe the endoscope, its intended use, and the directions for use should be provided with a specific intended use statement and any warnings, contraindications, or limitations clearly displayed as described in 21 CFR 807.87(e). The label of the device must bear the caution statement as outlined in 21 CFR 801.109(b)(1): "CAUTION: Federal law restricts this device to sale by or on the order of a physician."

A. Device labeling for the endoscope includes the device name, corporation name, address, telephone number, intended use, sterility status, sterility expiration date (if applicable), disposable/single use, a description of the device (including dimensional specifications), and directions for use.

1. The intended use statement should include specific indications. The anatomical sites, i.e. target organs, should be defined. Use of the generic intended use statements, provided in Section IV above, would be acceptable.

2. The directions for use should contain comprehensive instructions to include, but not necessarily be limited to descriptions of, how to prepare the endoscope for use, the functional test procedures which should be performed on the endoscope prior to use, and how to operate the endoscope. Maintenance and troubleshooting procedures should be outlined with instructions on how to perform the maintenance (including when to contact the manufacturer for routine maintenance), the frequency of the maintenance, and a corporation contact point if troubleshooting procedures fail.

3. Relevant contraindications, warnings, and precautions, should be included in the labeling of the device.

4. The directions for use should identify any required training (e.g., experience with endoscopy) prior to physician use.

5. Reprocessing information should be included for all reusable devices. See section IV.H. above for more information.

B. Advertisements or promotional literature for the endoscope should be provided. Literature or labeling may not imply approval by FDA in any manner. Guidance on labeling issues is described in Bluebook Memo G91-1 "Device Labeling Guidance (3/8/91)." A copy may be obtained from DSMA.

VI. Device Modifications.

Guidance concerning device modifications is available in the draft guidance entitled, "Deciding When to Submit a 510(k) for Change to an Existing Device (4/8/94)." A copy is available from DSMA.