Guidance for the Content of Premarket Notifications for Ureteral Stents (Text Only)

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.

A ureteral stent is described in the FDA regulation, 21 CFR 876.4620 (a), as a "tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. The device may have finger-like protrusions or hooked ends to keep the tube in place. It is used in the treatment of ureteral injuries and ureteral obstructions." The classification for this device is Class II as stated in 21 CFR 876.4620 (b) and its procode is 78 FAD - splint, ureteral. Examples of accessories for this device include a guidewire and a pusher (push catheter).

The primary reference for the information required to be in a premarket notification (510(k)) for a medical device is set forth in 21 CFR 807.87. The purpose of this regulation is to provide adequate documented information to determine substantial equivalence to a device in commercial distribution. Substantial equivalence is to be established with respect to, but not limited to, intended use, design, materials, performance, safety, effectiveness, labeling, and other applicable characteristics.

FDA recommends that each premarket notification for a ureteral stent include the following information in order to ensure that the submission is complete and will permit a determination of substantial equivalence:

I. The device name, including both the trade or proprietary name and the classification name (Ureteral Stent) of the device as described in 21 CFR 807.87 (a).

II. The establishment registration number, if applicable, of the owner or operator submitting the premarket notification as described in 21 CFR 807.87 (b).

III. The class (Class II) in which the device has been placed under section 513 of the act and the appropriate panel (78 Gastroenterology/Urology) as described in 21 CFR 807.87 (c).

IV. Action taken by the person required to register to comply with the requirements of the act under section 513 for Special Controls. Note that Special Controls are not currently required for ureteral stents under section 513 of the act.

V. The Safe Medical Devices Act of 1990 (SMDA) requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket

notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information.

VI. Proposed labels, labeling, and advertisements sufficient to describe the ureteral stent and its accessories, 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. A label includes any identification on the ureteral stent and on the package in which it is stored and shipped. The package device label should include the device name, U.S. point of contact, corporation name, address, and phone number. The package label should include all of the above, as well as sterility status, expiration date, disposable/single use, quantity enclosed, size (diameter and length), maximum implant duration, etc.

B. Device labeling for the ureteral stent and its accessories includes the intended use, a description of the device, and directions for use.

1. The intended use statement should include specific indications and the target population should be defined.

2. The directions for use should contain comprehensive instructions to include, but not necessarily be limited to, how to prepare the ureteral stent for use, how to place and remove the stent, maximum implant duration, visualization techniques, which parts of the set (i.e. stent, guidewire, and pusher) are single use/disposable or reusable, and functional test procedures for the ureteral stent prior to use. Troubleshooting procedures should be outlined and a corporation contact

point should be identified if troubleshooting procedures fail.

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

C. Advertisements or promotional literature for the ureteral stent that will accompany the device 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)" and a copy may be obtained from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance at (800) 638-3041 or (301) 443-6597.

VII. A Summary of Equivalence comparing similar devices legally in commercial distribution in the United States must be provided. This includes devices in commercial distribution prior to May 28, 1976, the enactment date of the Medical Devices Amendments, and any new devices introduced subsequently. A Summary of Equivalence includes similarities and differences between the device and the device to which it is compared. The ureteral stent should be compared to a legally marketed ureteral stent, including, but not limited to, the following: intended use, design (stent diameter, stent length, type of curls, curl diameter, drainage holes (size and distance between), trailing suture, etc., other applicable specifications), materials (e.g. catheter shaft, curls, guidewire, pusher, trailing suture, etc.), performance, and patient population justifying any new population cited.

State whether the substantially equivalent device is a pre-amendment device or a device which has been through the 510(k) process, providing the 510(k) document control number if known. The summary of equivalence information should be provided in a manner that is clear and comprehensible, e.g. tabular form.

VIII. For a device that has undergone a change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use (e.g. injection stent with adaptor and injection/release catheter), the 510(k) must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device, as described in 21 CFR 807.87 (g).

Significant modifications should be supported by a rationale for the modification with supporting documentation, including clinical or other valid scientific studies which demonstrate that these differences do not affect safety and effectiveness, as described in 21 CFR 807.87 (f).

The description of all ureteral stents and accessories should include any significant changes or modifications from the predicate device that could affect safety, effectiveness, or intended use. Provide any functional, animal, clinical, and/or any other testing data to support your claims. Provide certification regarding any compliance with voluntary standards, if applicable.

IX. The physical description of each ureteral stent to be marketed should be provided in the form of a labeled diagram, photograph/picture, schematic, etc., which includes all internal, external, etc. parts of the device. The physical description should include the specifications (length and diameter) of the ureteral stent and identifies any components which are disposable. The labeled diagram, photograph/picture, schematic, etc., should address the name and function of all parts of the ureteral stent (main shaft of stent, curls, drainage holes, markings, etc.).

If the ureteral stent is sold in a set that includes accessories, these accessories need to be identified and reviewed along with the ureteral stent and require the same types of information as stated above. These accessories might include a guidewire, pusher, etc. Labeling must state whether the accessory is intended for single use and whether it is reusable or disposable.

X. An exact identification of all materials used to fabricate the ureteral stent and its accessories should be provided and a statement regarding any material differences from the pre-amendment or substantially equivalent ureteral stent should be explicitly stated. If the materials are identical to the pre-amendment or substantially equivalent device and are identically processed and sterilized, then this should be explicitly stated. The sponsor will need to provide biocompatibility testing data on any material changes that have been implemented. Ureteral stents are considered to be a long-term mucosal contacting implant and testing should include, but is not limited to, mucosal irritation, sensitization, cytotoxicity, chronic systemic toxicity, and implantation. Implantation testing should reflect the recommended implant duration in labeling.

Guidance for the testing is provided in the document entitled "Tripartite Biocompatibility Guidance for Medical Devices" and a copy may be obtained from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

An exact identification of all colors (ink, dyes, markings, radiopaque material, etc.) used to fabricate the ureteral stent and its accessories should be provided and a statement regarding any colorant changes from the pre-amendment or substantially equivalent ureteral stent should be included. If the colors are identical to the pre-amendment or substantially equivalent device then this should be explicitly stated. The sponsor will need to provide biocompatibility testing data on any colorant changes that have been implemented; state how the markings are processed (etched, bands, in material, etc.) and whether the color contacts skin, mucosa, etc.

XI. The following data should be provided to demonstrate substantial equivalence of your ureteral stents with respect to functional performance. These tests should be conducted on all sizes and in a manner as similar as possible to how the ureteral stent will be used in a medical/surgical procedure (i.e. at body temperature and in a simulated body fluid). In addition, the ureteral stents to be tested must have been sterilized according to the validated sterilization process that is to be used for the marketed device, because sterilization may affect the device properties.

A. Flow Rate: The flow rate in a stent at a given head pressure is dependent upon the inside diameter of the stent and the properties of the fluid passing through it. This test should demonstrate the rate at which urine will flow through the stent. A statistically valid number of stents should be tested to establish the flow rate of each stent size. A sampling of stents representative of the product line, e.g. largest, smallest, longest, and shortest, should be tested. Testing should be conducted in accordance with accepted industry standards, e.g. ASTM F-623-89 (modified as needed), and explicitly stated as such, or a description and analysis of the test procedures used should be provided justifying their validity.

B. Elongation/Yield and Tensile Strength: These tests should demonstrate the percent elongation of the stent before deformation, i.e. cracking or stretching, and the point at which the stent tears or breaks, i.e. tensile strength. A statistically valid number of stents should be tested to establish the elongation and tensile strengths. Again, a

sampling of stents representative of the product line should be tested. Testing should be conducted in accordance with accepted industry standards, e.g. ASTM D412, and explicitly stated as such, or a description and analysis of the test procedures used should be provided justifying their validity.

C. Curl Strength: Curl strength is the measure of force required to straighten a curl of the stent and this test should demonstrate the point at which the curl straightens. In addition, curl strength is considered to be directly related to a stent's resistance to migration. A statistically valid number of stents should be tested to establish the curl strength of each curl size. Again, a sampling of stents representative of the product line should be used. Testing should be conducted in accordance with accepted industry standards and explicitly stated as such, or a description and analysis of the test procedures used should be provided justifying their validity.

D. Coefficient of Friction: This test is optional for uncoated catheters. This test is used to establish the effect of a lubricious or other type of coating on a stent where it is claimed that the coating is to reduce friction and promote ease of placement. Again, a statistically valid number of stents should be tested to establish the coefficient of friction. Testing should be conducted in accordance with accepted industry standards, e.g. ASTM D1894, and explicitly stated as such, or a description and analysis of the test procedures used should be provided justifying their validity.

E. Data that demonstrates whether the coating(s), if applicable, cause some change in the make-up of the underlying stent materials.

F. Shelf Life/Expiration Date: Testing demonstrating that long periods of storage and adverse shipping conditions do not result in alterations of the coating(s) or its properties.

XII. Complete information regarding ureteral stents and its accessories that are sold sterile must be provided and must include sterilization method; validation method; packaging materials and a description of the packaging to ensure sterility is maintained; sterility assurance level (SAL), and radiation dose or the maximum levels of residuals of ethylene oxide, ethylene chlorohydrin, and ethylene glycol which remain on the device, whichever applicable. If the device will be labeled as pyrogen

free, or non-pyrogenic, provide a description of the method used to make that determination (LAL or Rabbit test). Guidance on sterility issues is described in ODE Bluebook Memo K90-1 510(k) "Sterility Review Guidance (2/12/90)" and a copy may be obtained from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

If the ureteral stent and its accessories are sold and labeled as nonsterile or can be reprocessed, instructions on cleaning, disinfection, and/or sterilization should be provided. Accessories that are disposable should be labeled as single use.

XIII. If this device is to be marketed as a kit, identify all components and provide the certification stated below:

I certify that the following components of my kit are either (1) legally marketed pre-amendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemptions from Section 510(k) of the act (e.g., 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 to be intended (i.e., I am not claiming or causing a new use for the component(s)).

I further certify that these components are not purchased in "bulk", but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-amendments, exemption, or premarket notification criteria and status.

If you cannot make the above referenced certification statement (first paragraph) for each component of your kit, you must itemize the components without a pre-amendments, exemption, or premarket notification status. In this case we will continue our premarket notification review of these components of your kit.

If you cannot make the above referenced certification statement (second paragraph) for each component of your kit, you must itemize these components, state whether they are pre-amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterile, package/repackage, label/relabel, etc.).

If the device kit contains components which are subject to regulation as drugs, a substantially equivalent determination will not apply to the drug component(s) of the device. For information on applicable Agency requirements for marketing the drug component(s) in the kit, it is suggested that you contact the Center for Drug evaluation and Research's Division of Drug Labeling Compliance at (301) 295-8063.

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)