Guidance For The Content Of Premarket Notifications For Urodynamic/Uroflowmetry Systems (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 urodynamic system is described in the FDA regulation, 21 CFR 876.1620 (a), as a "device used to measure volume and pressure in the urinary bladder when it is filled through a catheter with carbon dioxide or water. The device controls the supply of carbon dioxide or water and may also record the electrical activity of the muscles associated with urination. The device system may include transducers, electronic signal conditioning and display equipment, a catheter withdrawal device to enable a urethral pressure profile to be obtained, and special catheters for urethral profilometry and electrodes for electromyography. This generic type of device includes the cystometric gas (carbon dioxide) device, the cystometric hydraulic device, and the electrical recording cystometer, but excludes any device that uses air to fill the bladder." The classification for this device is Class II as stated in 21 CFR 876.1620 (b) and its procodes are: 78 EXQ - cystometer, electrical recording; 78 FAP - cystometric gas (carbon dioxide) or hydraulic device; and 78 FEN - device, cystometric, hydraulic.

A uroflowmetry system is described in the FDA regulation, 21 CFR 876.1800 (a), as a urine flow or volume measuring system "that measures directly or indirectly the volume or flow of urine from a patient, either during the course of normal urination or while the patient is catheterized. The device may include a drip chamber to reduce the risk of retrograde bacterial contamination of the bladder and a transducer and electrical signal conditioning and display equipment. This generic type of device includes the electrical urinometer, mechanical urinometer, nonelectric urinometer, disposable nonelectric urine flow rate measuring device, and uroflowmeter. The classification for this device is Class II as stated in 21 CFR 876.1800 (b) and its procodes are: 78 FFG - device, urine flow rate measuring, non-electrical, disposable; 78 EXS - urinometer, electrical; 78 EXR - urinometer, mechanical; 78 EXT - urinometer, non-electrical; and 78 EXY - uroflowmeter.

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, energy used/delivered, materials, performance, safety, effectiveness, labeling, and other applicable characteristics.

FDA recommends that each premarket notification for a urodynamic/uroflowmetry system 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 (Urodynamics Measurements System or Urine Flow or Volume Measuring System) 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 urodynamic/uroflowmetry systems 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 urodynamic/uroflowmetry system, 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 urodynamic/ uroflowmetry system 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 items, quantity enclosed, size, energy used, etc.

B. Device labeling for the urodynamic/uroflowmetry system 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 set up and prepare the urodynamic/ uroflowmetry system for use, how to operate the urodynamic/uroflowmetry system, how to stop operation, which parts are single use/disposable or reusable, functional test procedures for the urodynamic/ uroflowmetry system prior to use. Maintenance and troubleshooting procedures should be outlined with instructions on how to perform the maintenance, frequency, and a corporation contact point if troubleshooting procedures fail.

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

4. Patient labeling must also be provided for devices (e.g., ambulatory urodynamic monitors) intended to be used by patients outside the health care setting. This labeling should provide the patient with realistic expectations of device performance and potential complications and include instructions for use with appropriate warning and precautionary information.

C. Advertisements or promotional literature for the urodynamic/uroflowmetry system 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 urodynamic/uroflowmetry system should be compared to a legally marketed urodynamic/uroflowmetry system, including, but not limited to the following: intended use, design (hardware, software, detection parameters and accuracy, safety features, and other applicable characteristics), energy used/delivered, materials of all components identifying those that come into patient contact, performance, target population justifying any new population cited, and any other related information.

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, 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 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 the urodynamic/uroflowmetry system should include any significant changes or modifications from the predicate device that could affect safety, effectiveness, or intended use. Provide any bench, animal, clinical, functional, in vitro, and/or any other appropriate testing data to support your claims. Provide certification regarding any compliance

with voluntary standards, if applicable.

IX. The physical description of each urodynamic/uroflowmetry system to be marketed should be provided in the form of a labeled diagram, photograph/picture, schematic, etc., which includes all internal/external, assembled/unassembled, etc. parts of the urodynamic/uroflowmetry system. The physical description should include the specifications (length, width, height, diameter, weight, power requirements, and other applicable information) of the urodynamic/uroflowmetry system. The physical description should also identify any parts which are disposable (i.e., catheters, collection cups, and transducers). The labeled diagram, photograph/picture, schematic, etc., should address the name and function of all components of the urodynamic/ uroflowmetry system. Examples of these components include the micturition seat/stand, weight/load cell transducer, funnel, collection cups, EMG transducers, data collection unit, power supply, electrical adapters/outlets (e.g. for transducer connection), etc.

If the urodynamic/uroflowmetry system is sold in a set that includes accessories, these accessories need to be identified and reviewed along with the urodynamic/uroflowmetry system and require the same types of information as stated above. These accessories might include catheters, EMG transducers, and cavernosometry pump and accessories. (Note: cavernosometry devices are not yet covered by a classification regulation, but they have a procode of 78 LST - erectile dysfunction device). Labeling must state if the accessory is intended for single use and whether it is reusable or disposable. If any of the accessories have been previously marketed for the same intended use, provide certification of pre-amendment status or the 510(k) number, if known.

X. An exact identification of all materials used to fabricate the urodynamic/uroflowmetry system should be provided and a statement regarding any material differences from the pre-amendment or substantially equivalent urodynamic/uroflowmetry system should be explicitly stated. If the materials are identical to the pre-amendment or substantially equivalent device and are 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 or justify why this data is not needed, i.e. the material does not come into patient contact. 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 urodynamic/uroflowmetry system should be provided and a statement regarding any colorant changes from the pre-amendment or substantially equivalent urodynamic/uroflowmetry system should be included. If the colorants 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. Data should be provided to demonstrate substantial equivalence of your urodynamic/uroflowmetry system with respect to functional performance. Testing should be conducted in a manner as similar as possible to how the urodynamic/uroflowmetry system will be used in a medical procedure. A statistically valid number of urodynamic/uroflowmetry systems should be tested to establish the performance. 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.

Testing data validating stated accuracy, and functional tests that verify all features operate in accordance with specifications must be provided. System calibration should be explicitly addressed. Electromagnetic compatibility should be addressed, including the effects of voltage spikes or power fluctuations on system performance. For ambulatory systems, clinical or simulated use performance data that demonstrates accuracy and performance to specifications during a variety of patient activities must also be provided.

XII. Guidance for the information required in a premarket notification of a software controlled device is provided in the document entitled "Reviewer Guidance For Computer Controlled Medical Devices Undergoing 510(k) Review (Draft 2/1/91)" 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.

XIII. Complete information regarding urodynamic/uroflowmetry systems and

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 level 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). Note that devices or tubing that enter the blood stream (e.g. cavernosometry) must be provided pyrogen free. If the entire urodynamic/uroflowmetry system is not sold sterile and non-pyrogenic, labeling must clearly identify which parts are sterile and/or non-pyrogenic. 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 urodynamic/uroflowmetry system is sold and labeled nonsterile or can be reprocessed, instructions on disassembly, cleaning, disinfection, and/or sterilization should be provided. If appropriate, a statement that the urodynamic/uroflowmetry system requires high level disinfection should be provided and compatible solutions and/or procedures for high level disinfection and/or sterilization need to be identified. Accessories that are disposable should be labeled as single use.

XIV. 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)