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.

November 1, 1994

510(k) Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology

Note: General guidance for the preparation of a 510(k) submission is provided in the DRAERD "Draft Guidance for the Content of Premarket Notifications." This document is available from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

1. Administrative information: **Adequate**

a. Sponsor/manufacturer name and address ___

b. Establishment registration number ___

c. Device trade name ____

d. Procodes and Classification Names

Stone Dislodgers

Ureteral Stone Dislodger: 78 FFL, Class II, 21 CFR 876.4680 ____

Flexible Stone Dislodger (Urological): 78 FGO, Class II, 21 CFR 876.4680 ___

Biliary Stone Dislodger: 78 LQR, Class II, 21 CFR 876.5010 ___

Mechanical Lithotripters

Mechanical Biliary Lithotripter: 78 LQC, Class II, 21 CFR 876.4500 ____

Bladder Stone Tripsor: 78 FGK, Class II, 21 CFR 876.4500 ____

2. Reason for the 510(k) submission: (new device or a modification to an existing device) ____

3. Intended use of the device: ___

Stone dislodgers are intended to be used during urological and/or gastroenterological procedures to endoscopically grasp, manipulate and remove calculi and other foreign objects. Mechanical Lithotriptors are intended to grasp, crush and remove urinary and/or biliary stones.

4. Device Description:

a. List of device's component parts ___

b. Diagrams, drawings, photographs of the device ____

c. Description of operation ___

d. List of the ranges of sizes/models proposed for marketing ____

e. Explanation of whether the device or any of its parts are intended to be reused ___

If the device can be reused, evidence that it can withstand multiple cleanings and sterilizations, and certification that the reprocessing instructions have been scientifically validated ___

5. Proposed Labeling, instructions for use, advertisements:

a. Intended use statement (see section 3 above for acceptable wording) ___

b. Instructions for use ____

c. Prescription device statement (Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician) ___

d. Labeled for single use only (if applicable) ____

e. Labeled as sterile ___

f. Reprocessing (cleaning, disinfection and sterilization) instructions (if applicable) ____

6. Mechanical/physical testing of an appropriate number of final sterilized devices:

a. Stone capture testing to validate that the stone dislodger can successfully entrap and hold a stone when pulled through a clear plastic tube

which simulates the size and geometry of the urethra, ureter, and/or common bile duct. The sponsor should provide the diameter of the tube used and describe the rationale used for determining the appropriate tube diameter and geometry in this test. _____

b. Pull testing to determine the minimum amount of tensile load that the device can withstand without failing. The location and type of failure should be reported. This test should also be performed on a legally marketed predicate to demonstrate equivalence. ____

c. Flexibility testing to document that the distal portion of the device is able to withstand the 90◦ deflection necessary to pass through the working channels of some endoscopes. _____

d. For mechanical lithotripters, calculi crush testing to validate that the device can crush actual stones. If actual stones are not available, a substitute material may be used if the similarity of the fracture properties of the substitute and the actual stones is demonstrated. Stones should be crushed until device failure, with the fracture strength and type of failure recorded. If the

sponsor wishes to claim that more than one stone (or fragments of the same stone) can be crushed by one device, data to support this claim are needed. This crush testing should also be performed on a legally marketed predicate device to demonstrate equivalence. ____

7. Biocompatibility:

a. List of all device materials ____
b. For materials that contact either the mucosal tissue or infusion fluids (including adhesives or color additives), provide either:

i. Evidence that the same formulations of these materials are used in another, similar legally marketed device (provide the device name, manufacturer, and (if possible) 510(k) number); or ____

ii. The results of the following biocompatibility tests (minimum required) conducted on the final sterilized product

(1) mucosal irritation test ____

(2) sensitization assay ____

(3) cytotoxicity test ____

(4) acute systemic toxicity ____
(5) short term implantation test ____

8. Sterility information:

a. The method of sterilization ____
b. The method used to validate the sterilization cycle ____

c. The sterility assurance level (i.e. SAL) achieved by the sterilization cycle ____
d. For EtO sterilization, the residuals of ethylene oxide (EtO), ethylene glycol (EtG), and ethylene chlorohydrin (EtCh) ____
e. For gamma radiation sterilization, the radiation level (in megarads) used ____

f. A description of the packaging material used to ensure the sterility of the device ____

9. Comparison to legally marketed mechanical lithotripters and stone dislodgers:

a. Name/manufacturer of predicate device(s) ____
b. Labeling of the predicate device ____
c. Intended use of the predicate device ____
d. Description of the predicate device ____
e. Diagrams/ photographs of the predicate device ____
f. 510(k) number (if known) of the predicate device (or statement that the predicate device is preamendments) ____
g. A detailed comparison of the similarities and differences between the 510(k) device and the predicate device (in tabular format). Note that a comparison of the mechanical properties identified in Section 6 above should also be included. ____

10. 510(k) Summary/Statement: ____

For further information contact:

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