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Note: General guidance for the preparation of a 510(k) submission is provided in the DRAERD "Draft Guidance for the Content of Premarket Notifications."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:							
	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.	Reaso	on for the 510(k) submission: (new device or a modification to an existing device)							
3.	Inter	nded 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.	Devi	ce 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.	Propo	osed Labeling, instructions for use, advertisements:							
	a.	<pre>Intended use statement (see section 3 above for acceptable wording)</pre>							
	b.	Instructions for use							

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Page 3	510(k)	Chec	klist	for	Mechani	ical	Lithotripters	and	Stone
Dislodge	ers used	l in	Gastro	ente	erology	and	Urology		

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. <u>Flexibility testing</u> 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, <u>calculi crush testing</u> 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

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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.	Bioco	mpat	ib:	ili	ty:
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- 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

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f.	Α	desc	ript	ion	of	the	pac	kagi	ing	material	used	to
	er	isure	the	ste	eri]	lity	of	the	dev	<i>r</i> ice		

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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