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Display Date: 8-8-00
Publication Date: 8-9-00
Certifier: SNKeese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 98N–1134]

Gastroenterology and Urology Devices; Reclassification of the Extracorporeal Shock Wave Lithotripter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reclassify from class III to class II the extracorporeal shock wave lithotripter, when intended for use to fragment kidney and ureteral calculi. FDA is taking this action on its own initiative in order to assure that these devices are regulated according to the appropriate degree of regulatory control needed to provide reasonable assurance of their safety and effectiveness. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document, which will serve as the special control for the reclassified device.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the

Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition for the issuance of an order classifying the device in class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Section 216 of FDAMA replaced the ''four of a kind'' rule in the old section 520(h)(4) of the act (21 U.S.C. 360j(h)(4)) with a provision that frees safety and effectiveness data in PMA's approved 6 or more years earlier for use by the agency in certain actions, including device reclassifications. Under section 520(h)(4) of the act, as amended by FDAMA, the agency has supplemented other sources of information that support reclassification of the extracorporeal shock wave lithotripter with data contained in PMA's approved 6 or more years before the date of this rule. Although FDA has sufficient information to support this reclassification without relying upon data available under section 520(h)(4) of the act, the agency decided to use such data in taking this action. In this instance, the data used would have been available to the agency under the superseded four of a kind rule.

Under section 513(f)(2)(B)(i) of the act, the Secretary of Health and Human Services (the Secretary), for good cause shown, may refer a proposed reclassification to a device classification panel. The panel shall make a recommendation to the Secretary respecting approval or denial of the proposed reclassification. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the proposed reclassification was initiated.

II. Response to Comments

FDA referred the issue of reclassification of the extracorporeal shock wave lithotripter to the Gastroenterology and Urology Devices Advisory Panel (the Panel) for review and recommendation. At a public meeting on July 30, 1998, the Panel unanimously recommended that the extracorporeal shock wave lithotripter indicated for the fragmentation of kidney and ureteral calculi be reclassified from class III to class II. The Panel believed that the special controls of consensus standards, clinical performance testing, labeling restrictions, and physician training restrictions would provide reasonable assurance of the safety and effectiveness of the device. In the **Federal Register** of February 8, 1999 (64 FR 5987), FDA published a summary of the Panel recommendation and a proposed rule to reclassify the extracorporeal shock wave lithotripter. FDA invited interested persons to submit written comments by May 10, 1999. FDA received one comment that raised several issues. The following is FDA's response to the issues raised by the comment.

(Comment 1) The comment suggested that FDA should identify the PMA's and PMA supplements that FDA relied upon in reclassifying the device and make the summaries of safety and effectiveness for those submissions available in the Dockets Management Branch.

FDA agrees. The PMA's that FDA relied upon are listed in section VII ''References'' below and the summaries of safety and effectiveness are available in the Dockets Management Branch, as stated there. Section 520(h)(4)(b) of the act states that the summaries of safety and effectiveness shall be available for use by FDA as the evidentiary basis for a reclassification action. FDA notes, however, that section 520(h)(2) of the act provides that the summaries of safety and effectiveness may not be used to establish the safety or effectiveness of another device by any person other than the person who submitted the information. In the case of certain supplements for which a summary of safety and effectiveness was not prepared, FDA will make available a redacted version of the supplement.

(Comment 2) The comment questions whether FDA believes that section 520(h)(4) of the act allows for the use of information from PMA supplements as well as original PMA's.

Yes. Section 520(h)(4) of the act authorizes FDA to use data contained in applications for premarket approval submitted under section 515(c) of the act. The 6-year provision, then, applies equally to initial PMA submissions and PMA supplements, which are applications for premarket approval of a changed device and are submitted under section 515(c) of the act, the general PMA authority.

(Comment 3) The comment also said that persons submitting a premarket notification (510(k)) other than holders of approved PMA's and PMA supplements should only be able to use as predicate devices model numbers or modified versions of extracorporeal shock wave lithotripters legally marketed under a 510(k), PMA, or PMA supplement no sooner than 6 years before the applicant's 510(k) submission for a new or modified device. Holders of an approved PMA or PMA supplement should be the only applicants permitted to cite as a predicate the device for which they have an approved application fewer than 6 years old.

FDA disagrees with this comment. Section 513(i) of the act provides that substantial equivalence may be determined based upon comparison with any legally marketed device. The intent of section 520(h)(4) of the act is to provide an additional source of information upon which certain actions can be based. Section 520(h)(4) of the act does not place any limitations on the type of device that may be used as a predicate device.

(Comment 4) The comment said that the indications for use in the proposed rule are inconsistent with those in the approved PMA's and PMA supplements to date. The comment also said that the labeling restrictions in the rule do not address indications for use and questioned how manufacturers may switch to the broad intended use in the rule.

FDA disagrees. The intended use in the rule (i.e., "fragmentation of urinary calculi within the kidney and ureter") is consistent with prior approvals. Although some devices were restricted in their intended use to certain stone locations or size ranges based on the results or circumstances of their specific clinical studies, others had adequate data supporting the more general intended use. Therefore, the broad intended use in the rule incorporates both of the individual intended

uses that have been approved to date. This approach was based on findings in the literature that the differences in intended use of approved lithotripters were not primarily related to differences in technological characteristics. Because FDA is reclassifying a broad intended use, FDA believes that it is appropriate to list the various stone characteristics known to be associated with reduced effectiveness as precautions in the labeling. Manufacturers who have cleared devices with the limited intended uses can seek clearance to market their devices for the broad intended use by submitting a 510(k) comparing the device to a predicate that has the broad intended use.

(Comment 5) The comment noted that the guidance suggests that a confirmatory clinical study should enroll at least 20 patients at 2 sites. The comment questioned whether this means 20 patients at each site or 20 patients total at both sites. The comment further said that, in either case, the number is insufficient. The comment suggested that FDA should require 30 patients each at 3 sites and the study should include an assessment of treatment success and adverse effects immediately post-procedure and at 2 weeks and 1 month thereafter.

The guidance has been revised to clarify that clinical testing of devices that are similar in technological characteristics to legally marketed devices should include at least 20 patients total at 2 sites. FDA disagrees with the comment that there is a need to assess device safety and effectiveness outcomes in a statistically justified sample size. FDA believes that clinical testing in these circumstances is intended only to confirm device functionality and the adequacy of the proposed labeling rather than to assess device safety and effectiveness. FDA believes that the characterization testing described in the guidance is sufficient to demonstrate safety and effectiveness with respect to clinical outcomes for devices with similar technological characteristics. As noted in the proposed rule and guidance document, however, 510(k)'s for devices that have different technological characteristics from legally marketed predicates will likely require larger, statistically justified, clinical studies to investigate the effect of the new technological characteristics on safety and effectiveness outcomes. For these cases, the study design should be tailored to the

specifics of the new characteristics; therefore, we do not believe that a standard detailed study design should be spelled out.

(Comment 6) The comment suggested that the restricted device legend for the device should be revised to read: ''CAUTION: Federal law restricts this device to sale, distribution, and use only upon the lawful order of a physician trained and/or experienced in the use of this device as outlined in the required training program.'' The comment also suggested that this statement should be included in the regulation and not just in the guidance.

FDA agrees in part with this comment. FDA has added the words ''distribution or use'' after ''sale'' so as to track the language in section 520(e) of the act. FDA does not believe that it would not be correct to replace the phrase ''appropriate training program'' with ''required training program'' as suggested by the comment, because FDA does not regulate all aspects of the training program. Also, FDA does not believe that it is necessary to add the language to the regulation, because the requirement is already covered by 21 CFR 801.109(b)(1). FDA has decided not to include the labeling in an appendix to § 876.5990 (21 CFR 876.5990). Instead, the labeling will be included in the guidance document only. FDA also slightly revised the identification section in § 876.5990(a) by removing the words ''through a water-filled rubber cushion or by direct contact of the patient's skin with the water'' and replacing them with ''using an appropriate acoustic interface.''

III. Final Rule

Therefore, FDA is finalizing the rule reclassifying the extracorporeal shock wave lithotripter into class II with the FDA guidance document entitled ''Guidance for the Content of Premarket Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi,'' as the special control. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the guidance document.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the reclassification action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order. The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace at lower costs. The agency therefore certifies that this reclassification action will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of $100 million or more on either the private sector or state, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public. Therefore, no burden is placed on the public.

VII. References

The following references have been placed on display in the Dockets Management Branch, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. P840008/S24, MFL 5000 Lithotripter, Dornier Medical Systems, Inc., July 3, 1991.

2. P840008/S26, MFL 9000 Lithotripter, Dornier Medical Systems, Inc., August 12, 1991.

3. Summary of Safety and Effectiveness, P890013, Piezolith Lithotripter, Model 2300, Richard Wolf Medical Instruments Corp., September 9, 1991.

4. Summary of Safety and Effectiveness, P880042, LT.01 Lithotripter, EDAP International Corp., December 12, 1991.

5. Summary of Safety and Effectiveness, TP890006, Therasonic Lithotripsy Treatment System, Diasonics, Inc., December 20, 1991.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.5990 is added to subpart F to read as follows:

§ 876.5990 Extracorporeal shock wave lithotripter.

(a) *Identification.* An extracorporeal shock wave lithotripter is a device that focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi within the kidney or ureter. The primary components of the device are a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the urinary stone is targeted using either an integral or stand-alone localization/imaging system. Shock waves are typically generated using electrostatic spark discharge (spark gap), electromagnetically repelled membranes, or piezoelectric crystal arrays, and focused onto the stone with either a specially designed reflector, dish, or acoustic lens. The shock waves are created under water within the shock wave generator, and are transferred to the patient's body using an appropriate acoustic interface. After the stone has been fragmented by the focused shock waves, the fragments pass out of the body with the patient's urine.

(b) *Classification*. Class II (special controls) (FDA guidance document: ''Guidance for the Content of Premarket Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureterai Calculi.'')

Dated: 7/12/00
July 12, 2000

Linda S. Kahan

Linda S. Kahan,
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[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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