Guidance for Industry

Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi

Draft Guidance – Not for Implementation

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U.S. Department of Health and Human Services
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Center for Devices and Radiological Health

Urology and Lithotripsy Devices Branch
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation

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Preface

Public Comment:

Comments and suggestions regarding this draft document should be submitted by **[date 90 days from release date]** to Docket N**[fill in]**, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 12420 Parklawn Drive (HFA-305), Room 1-23, Rockville, MD 20857.

Additional Copies:

World Wide Web/CDRH home page at http://www.fda.gov/cdrh/ode/swlguid.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1226 when prompted for the document shelf number.

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1. Introduction

A. Background

The purpose of this guidance document is to identify the information that should be provided to the Food and Drug Administration (FDA) in a premarket notification (510(k)) to support a determination of substantial equivalence for an extracorporeal shock wave lithotripter (SWL).

Note: ***This guidance is a draft of the document FDA proposes to issue in support of reclassification of the extracorporeal shock wave lithotripter into class II (special controls), should the proposed reclassification result in a final rule reclassifying such devices. The special controls cited within this document are those currently proposed by FDA. Extracorporeal shock wave lithotripters remain subject to premarket approval unless and until reclassified by FDA.***

B. Device Design/Principle of Operation

An SWL system focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi (i.e., kidney and ureteral stones). SWL systems incorporate a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the stone is targeted using either an integral or stand-alone localization/imaging system. Shock waves are typically generated using one of three methods: (1) electrostatic spark discharge (spark gap), (2) electromagnetically repelled membranes, or (3) piezoelectric crystal arrays; the shock waves are then focused onto the stone with either a specially designed reflector/dish or acoustic lens. The shock waves are created under water by the shock wave generator, and are transferred to the patient's body through either a water-filled rubber cushion or by direct contact of the patient's skin with the water. Once the stone is fragmented by the focused shock waves, the fragments pass out of the body with the patient's urine.

SWL devices are available in stationary, mobile, and transportable configurations. Stationary systems are indicated for use in a single health care facility. Mobile devices are permanently housed in a mobile trailer, which functions as a mobile lithotripsy suite and can be driven from site to site. Transportable devices are also intended to be driven from site to site, but unloaded and transported into the health care facility for patient treatment.

C. Regulatory History

SWL devices are post-amendment devices, and, therefore, were originally classified into class III by section 513(f) of the Federal Food, Drug, and Cosmetic Act ("the act"). On **[date]**, FDA published a final rule in the Federal Register reclassifying SWL devices into class II (**XX FR XXXXX**).

D. Devices Not Included

This guidance document only addresses SWL devices that are indicated for the fragmentation of urinary calculi in the kidney or ureter. Devices with other indications, such as biliary/gallstone lithotripsy or orthopedic lithotripsy, are currently class III and are not included within the scope of this guidance.

E. Additional Sources of Information

General guidance concerning the information required to be in a 510(k) may be obtained from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597, or at its Internet address (*http://www.fda.gov/cdrh/dsma/dsmamain.html#contents*).

For further information, contact DSMA or:

Urology and Lithotripsy Devices Branch (ULDB)
Division of Reproductive, Abdominal, Ear, Nose
and Throat, and Radiological Devices
Center for Devices and Radiological Health
9200 Corporate Boulevard (HFZ-470)
Rockville, Maryland 20850
(301) 594-2194 (phone)
(301) 594-2339 (fax)

2. Sponsor/Device Identification

FDA regulations (21 CFR 807.87) prescribe information that must appear in each 510(k) submission. This information includes:

A. Sponsor/Manufacturer Information

The name, contact person, address, telephone number, and (if available) facsimile number of both the sponsor of the 510(k) application and (if different from the sponsor) the device manufacturer.

B. Proposed Device

The trade or proprietary name of the device proposed for marketing, as well as the common device name, i.e., extracorporeal shock wave lithotripter

C. Predicate Device

The legally marketed device(s) to which the proposed device is being compared. To be as specific as possible, the 510(k) should include the following information to identify each predicate device and support the claim of substantial equivalence:

- Trade/proprietary name,
- Model number,
- Manufacturer,
- 510(k)/PMA reference number (if known),
- Intended use,
- Technological characteristics/performance specifications, and
- Labeling.

3. Classification/Product Code

The Code of Federal Regulations (CFR) number, regulatory class, and product code applicable to the extracorporeal shock wave lithotripter (listed below) should be provided in the 510(k):

- CFR Number: 21 CFR 876.**XXXX** ***(to be determined in the final rule)***
- Regulatory Class: Class II (special controls)
- Product Code: 78 LNS

4. Special Controls

As stated in the final rule reclassifying extracorporeal shock wave lithotripters into class II (**XX FR XXXXX**), SWL devices are subject to the following special controls:

- labeling restrictions (see Section 9.B.), and
- this guidance document†.

† *This guidance document describes a means by which SWL devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that this document is one factor that must be used in determining a proposed SWL device's substantial equivalence to a predicate device. Therefore, manufacturers attempting to establish that their device is substantially equivalent to a predicate SWL device must demonstrate that the proposed device complies with either the specific recommendations of the guidance or some alternate control that provides equivalent assurances of safety and effectiveness.*

5. Device Description

A. Reason for 510(k)

The sponsor should clearly state the reason for the submission of the 510(k), e.g., new SWL system, change in intended use, or design modifications to an existing SWL system.

B. Intended Use

The 510(k) should provide a clear statement of the proposed device's intended use, such as:

> "The [*device trade name*] is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter)."

The intended use should be identically worded in the following sections of the 510(k):

- the physician's labeling,
- the "Indications for Use" form, and
- (if provided) the "510(k) Summary."

C. Technical Characteristics

The sponsor should provide a technical summary of the device (or device modification, if applicable) and its major components. This section of the 510(k) should include, but not necessarily be limited to, the following information:

- General overview of the entire SWL system.
- Diagrams of the SWL system and its major components.
- Description of all safety features.
- Description of each of the SWL system's major components/subassemblies.
- Description of the localization procedure, its accuracy, and user calibration method.
- Description of the system's software/firmware (if applicable) in accordance with the FDA guidance document entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (5/29/98) (available from DSMA or its Internet address).
- Summary of the device's acoustic output, as described in Section 8.A., "Performance Testing."
- Description of the method(s) used to verify electrical safety and electromagnetic compatibility.
- Comparative descriptions of each of the device configurations for which marketing clearance is proposed (i.e., stationary, mobile, and transportable versions), as well as descriptions of the following (as applicable): installation requirements, site requirements, room/mobile suite requirements, and transportation vehicle specifications.

For new models of SWL devices, this technical summary should also include the information requested on the "SWL Specifications Sheet" (Appendix 1). For device modifications, however, the sponsor should only supplement the technical summary with the information from the "SWL Specifications Sheet" that is applicable to the particular technological change(s) being proposed in the 510(k).

6. Claim of Substantial Equivalence

In order to permit a determination of substantial equivalence, all intended uses, technological characteristics, performance test results, and labeling should be compared to a legally marketed device. It is recommended that such comparisons include the technical information requested in the "SWL Specifications Sheet" (Appendix 1), and be presented in tabular format.

7. Conformance to Standards

Manufacturers of SWL systems should conform to the following consensus standards:

- IEC 60601-2-36, "Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy" (1997).

- IEC 61846, "Ultrasonics - Pressure pulse lithotripters - Characteristics of fields" (1998).

Conformance to the above standards can be accomplished by submitting "declarations of conformity" in the 510(k). For guidance on the preparation of declarations of conformity to recognized standards, manufacturers should refer to the following documents (available from DSMA or the listed CDRH Internet addresses):

> "A New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" (3/20/98).
> (*http://www.fda.gov/cdrh/ode/parad510.html*)
>
> "Guidance on the Recognition and Use of Consensus Standards" (2/19/98).
> (*http://www.fda.gov/cdrh/modact/k982.html*)

8. Performance Testing

Manufacturers of SWL devices should submit the results of the following performance tests to demonstrate substantial equivalence between the proposed and predicate devices:

A. Shock Wave Characterization Measurements

[NOTE: *Measurements of shock wave characteristics, as described in Section 8.A. of the guidance, should be submitted in 510(k)s for (1) new SWL systems or (2) modifications to the specifications of the shock wave generator, high voltage generator, or focusing mechanism of an existing device. If the 510(k) is being submitted for other changes to the device or its labeling, however, the sponsor should only reference the shock wave characterization measurements that were submitted in a previous marketing application for the existing device model.*]

The purpose of this test is to quantify those shock wave characteristics that are believed to contribute to stone fragmentation and adverse tissue effects, and, thus, are indicators of clinical performance. These acoustic quantities (listed below) should be measured/calculated using the methodology described in the consensus standard IEC 61846 "Ultrasonics - Pressure pulse lithotripters - Characteristics of fields" (1998). Furthermore, these acoustic quantities should be reported for minimum, typical, and maximum shock wave generator output settings, and (to the extent possible) compared to those reported for the predicate device(s).

- Peak-positive acoustic pressure
- Peak-negative acoustic pressure
- Rise time
- Compressional pulse duration
- Maximum focal width
- Orthogonal focal width
- Focal extent
- Focal volume
- Distance between the focus and target location
- Derived focal acoustic pulse energy
- Derived acoustic pulse energy

NOTE: *The above acoustic quantities are defined in Clause 3 of IEC 61846.*

To facilitate comparison of this information to that of the identified predicate SWL system(s), FDA recommends that these acoustic quantities be reported in standard metric units of measure, and summarized in tabular format with accompanying graphs/plots attached.

B. Assessment of Localization Accuracy

[NOTE: *The assessment of localization accuracy, as described in Section 8.B. of the guidance, should be submitted in 510(k)s for (1) new SWL systems or (2) modifications to either the spatial position of the shock wave focus or the specifications of the localization/stone targeting system of an existing device. If the 510(k) is being submitted for other changes to the device or its labeling, however, the sponsor should only reference the localization accuracy assessment that was submitted in a previous marketing application for the existing device model.*]

The purpose of this test is to verify that the localization/stone targeting system is capable of locating the shock wave focus with sufficient accuracy to target stones as small as 4 mm in largest dimension within the focal volume. For this test, the manufacturer should quantitatively assess the maximum deviation of the "target location" (*i.e., the location in space where the manufacturer intends the operator to locate the stone*) from the "shock wave focus" (*i.e., the point of peak-positive acoustic pressure*) after aligning the localization/stone targeting system with the shock wave focus in accordance with the pretreatment procedures described in the device's instructions for use. This evaluation includes measurement of the distance between the focus and target location, as defined in Section 8.A. of this guidance, along with an assessment of the errors/uncertainties inherent in the localization/stone targeting system and acoustic measurements.

C. Road Testing

[NOTE: *Road testing, as described in Section 8.C. of the guidance, only applies to 510(k)s for SWL systems that are seeking marketing clearance for mobile and/or transportable use.*]

The purpose of this test is to verify that the mobile/transportable SWL system can withstand the stresses and vibrations experienced during unloading, set-up, transportation, loading, and stowing without significant degradation in performance specifications. The following information should be considered when designing this test:

- Using a final SWL system, baseline measures of the (1) mean peak-positive acoustic pressure at the shock wave focus at the typical shock wave generator output setting (n=30 shocks), (2) localization/stone targeting system accuracy, and (3) overall system functionality should be obtained. (Since only relative measures of peak-positive acoustic pressure are needed for this test, robust hydrophones, such as tourmaline crystal models, may be used.)
- Prepare the device for transport, consistent with the directions specified in the labeling.
- Perform a road test of the device by transporting the device for at least 1 hour. The course used for this test should represent a worst-case scenario, e.g., speed bumps, train tracks, sudden application of the breaks, highways, secondary and gravel roads, stop-and-go traffic, etc.
- Prepare the device for use, consistent with the directions specified in the labeling.

- Repeat the baseline tests of (1) mean peak-positive acoustic pressure at the shock wave focus at the typical shock wave generator output setting (n=30 shocks), (2) localization/stone targeting system accuracy, and (3) overall system functionality. (The post-road test measurement of peak-positive pressure should be performed using the same hydrophone design used during the baseline measurements.) These test results should be compared to those obtained prior to the road test, and should demonstrate that there is no difference in system performance specifications before and after transportation.

D. Clinical Performance Testing

[NOTE: *Clinical performance testing, as described in Section 8.D. of the guidance, should be submitted in 510(k)s for (1) new SWL systems; (2) modifications to the specifications of the shock wave generator, high voltage generator, or focusing mechanism of an existing device; or (3) the addition of clinical performance claims to the labeling of an existing device. If the 510(k) is being submitted for other changes to the device or its labeling, however, the sponsor should only reference the clinical performance testing that was submitted in a previous marketing application for the existing device model.*]

Clinical performance testing, as described in this section, should take the form of either a confirmatory clinical study or a larger clinical investigation of safety and effectiveness, depending upon the technological characteristics of the particular device.

If the proposed SWL system (1) employs a similar mechanism of action for the generation of shock waves as compared to predicate SWL systems, and (2) has shock wave characteristics (specified in Section 8.A. of this guidance) that are within the range of predicate SWL systems, a confirmatory clinical study should be performed to demonstrate substantial equivalence. The following information should be considered when designing a confirmatory clinical study:

- The objectives of this clinical study are to confirm the functionality of the device and adequacy of the proposed labeling.
- The study should enroll a minimum of 20 patients with urinary stone disease at 2 investigational sites, with follow-up at 1-week post-procedure. All subjects should be candidates for SWL, and should satisfy the device's proposed indications and contraindications for use.
- Investigators should record appropriate data during the SWL treatment session and at the 1-week follow-up exam to document the operational status of the device, such as:
  - ◊ the incidence, cause, and resolution of device malfunctions;
  - ◊ treatment parameters used;
  - ◊ stone fragmentation results;
  - ◊ the incidence of complications;

- ◊ anesthesia/analgesia usage;
- ◊ radiation exposure; and
- ◊ evaluation of system ergonomics.

On the other hand, if the proposed SWL system (1) employs a new mechanism of action for the generation of shock waves as compared to predicate SWL systems, or (2) has shock wave characteristics that are outside of the range of predicate SWL systems (as measured in Section 8.A. of this guidance), a larger clinical investigation should be performed to demonstrate that the new technological characteristics are as safe and as effective as those of the predicate device. When planning a large-scale clinical trial, consult the Urology and Lithotripsy Devices Branch for guidance on the appropriate study design to address the particular technological characteristics offered by the proposed device.

Lastly, if the sponsor is requesting the addition of device-specific claims regarding the clinical performance of the SWL system, clinical data sufficient to statistically support such claims should be submitted. Consult the Urology and Lithotripsy Devices Branch for guidance on the appropriate study design to address the particular clinical performance claims proposed for the SWL system.

Any U.S. clinical investigation of a SWL system that is not legally marketed must be conducted in accordance with the investigational device exemptions (IDE) regulations for a significant risk device. Reports of foreign clinical experience are acceptable provided that the investigation was conducted in accordance with the provisions of the IDE regulations regarding the protection of human research subjects (commonly referred to as the "Declarations of Helsinki"), and the data are applicable to the U.S. population and medical practice.

9. Labeling

A. General Labeling Considerations

Proposed labels, labeling, operator's manuals, and any promotional information sufficient to describe the proposed extracorporeal shock wave lithotripter, its intended use, and its directions for use should be submitted in the 510(k), consistent with 21 CFR 807.87(e). The label of the device packaging must bear the prescription device statement in accordance with 21 CFR 801.109(b)(1) and under the authority of section 515(d)(1)(B)(ii) of the act:

> "CAUTION: Federal law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program."

Listed below are available sources that may provide useful information regarding the information to be included in the labeling of medical devices: (1) "Device Labeling Guidance," ODE Blue Book Memorandum #G91-1; and (2) "Labeling: Regulatory Requirements for Medical Devices," HHS Publication FDA 89-4203. This information is available from DSMA.

B. Labeling Requirements Specific to SWL Systems

Labeling requirements, as described in this section, have been identified as a special control for extracorporeal shock wave lithotripters. Specifically, the labeling for the proposed SWL device must include the following Contraindications, Warnings, Precautions, Patient Selection and Treatment, and Adverse Events information, in addition to other appropriate labeling information:

Contraindications:

Do not use the device in patients with:

- Confirmed or suspected pregnancy.
- Coagulation abnormalities (as indicated by abnormal prothrombin time, partial thromboplastin time, or bleeding time) or those currently receiving anticoagulants (including aspirin).
- Arterial calcification or vascular aneurysm in the lithotripter's shock wave path.
- Urinary tract obstruction distal to the stone.
- Anatomy which precludes focusing the device at the target stone, such as severe obesity or excessive spinal curvature.

Warnings:

Anticoagulants: Patients receiving anticoagulants (including aspirin) should temporarily discontinue such medication prior to extracorporeal shock wave lithotripsy to prevent severe hemorrhage.

Cardiac monitoring: Always perform cardiac monitoring during lithotripsy treatment, since the use of extracorporeal shock wave lithotripsy has been reported to cause ventricular cardiac arrhythmias in some individuals. This warning is especially important for patients who may be at risk of cardiac arrhythmia due to a history of cardiac irregularities or heart failure.

Cardiac arrhythmia during treatment: If a patient experiences cardiac arrhythmia during treatment at a fixed shock wave repetition rate, shock wave delivery should either be terminated or switched to an ECG-gated mode (i.e., delivery of the shock wave during the refractory period of the patient's cardiac cycle). As a general practice, patients with a history of cardiac arrhythmia should be treated in the ECG-gated mode. [*If the system is capable of delivering shock waves at a fixed frequency.*]

Pacemaker or implantable defibrillator: To reduce the incidence of malfunction to a pacemaker or implantable defibrillator, the pulse generator should be programmed to a single chamber, non-rate responsive mode (pacemakers) or an inactive mode (implantable defibrillators) prior to lithotripsy, and evaluated for proper function post-treatment. Do not focus the lithotripter's shock wave through or near the pulse generator.

Bilateral stones: Do not perform bilateral treatment of kidney stones in a single treatment session, because either bilateral renal injury or total urinary tract obstruction by stone fragments may result. Patients with bilateral kidney stones should be treated using a separate treatment session for each side. In the event of total urinary obstruction, corrective procedures may be needed to assure drainage of urine from the kidney.

Air-filled interfaces in shock wave path: Do not apply shock waves to air-filled areas of the body, i.e., intestines or lungs. Shock waves are rapidly dispersed by passage through an air-filled interface, which can cause bleeding and other harmful side effects.

Infected stones: Prophylactic antibiotics should be administered prior to treatment whenever the possibility of stone infection exists. Extracorporeal shock wave lithotripsy treatment of pathogen-harboring calculi could result in systemic infection.

Cardiac disease, immunosuppression, and diabetes mellitus: Prophylactic antibiotics should be administered prior to extracorporeal shock wave lithotripsy treatment to patients with cardiac disease (including valvular disease), immunosuppression, and diabetes mellitus, to prevent bacterial and/or subacute endocarditis.

Precautions:

Renal injury: To reduce the risk of injury to the kidney and surrounding tissues, it is recommended that: (1) the number of shock waves administered during each treatment session be minimized; (2) retreatment to the same kidney/anatomical site occur no sooner than 1 month after the initial treatment; and (3) each kidney/anatomical site be limited to a total of three treatment sessions.

Radiographic follow-up: All patients should be followed radiographically after treatment until stone-free or there are no remaining stone fragments which are likely to cause silent obstruction and loss of renal function.

Impacted or embedded stones: The effectiveness of extracorporeal shock wave lithotripsy may be limited in patients with impacted or embedded stones. Alternative procedures are recommended for these patients.

Staghorn stones: The effectiveness of extracorporeal shock wave lithotripsy may be limited in patients with either staghorn or large (> 20 mm in largest dimension) stones. Alternative procedures are recommended for these patients.

Small ureteral stones: Small middle and lower ureteral stones, 4 to 6 mm in largest dimension, are likely to pass spontaneously. Therefore, the risks and benefits of extracorporeal shock wave lithotripsy should be carefully assessed in this patient population.

Patient Selection and Treatment:

Children: The safety and effectiveness of this device in the treatment of urolithiasis in children have not been demonstrated. Although children have been treated with shock wave therapy for upper urinary tract stones, experience with lithotripsy in such cases is limited. Studies indicate that there are growth plate disturbances in the epiphyses of developing long bones in rats subjected to shock waves. The significance of this finding to human experience is unknown.

Women of childbearing potential: The treatment of lower ureteral stones should be avoided in women of childbearing potential. The application of shock wave lithotripsy to this patient population could possibly result in irreversible damage to the female reproductive system and to the unborn fetus in the undiagnosed pregnancy.

Adverse Events:

Potential adverse events associated with the use of extracorporeal shock wave lithotripsy include those listed below, categorized by frequency and individually described:

Potential Adverse Events of Extracorporeal Shock Wave Lithotripsy

Commonly reported (> 20% of patients)

- Hematuria
- Pain/renal colic
- Skin redness at shock wave entry site

Occasionally reported (1-20% of patients)

- Cardiac arrhythmia
- Urinary tract infection
- Urinary obstruction/steinstrasse
- Skin bruising at shock wave entry site
- Fever (> 38°C)
- Nausea/vomiting

Infrequently reported (< 1% of patients)

- Hematoma (perirenal/intrarenal)
- Renal injury

Hematuria: Hematuria occurs following most treatments, is believed to be secondary to trauma to the renal parenchyma, and usually resolves spontaneously within 24 to 48 hours of treatment.

Pain/renal colic: Pain/renal colic commonly occurs during and immediately after treatment, and typically resolves spontaneously. Temporary pain/renal colic may also occur secondary to the passage of stone fragments, and can be managed with medication.

Skin redness at shock wave entry site: Skin redness at the shock wave entry site commonly occurs during and immediately after treatment, and typically resolves spontaneously.

Cardiac arrhythmia: Cardiac arrhythmias, most commonly premature ventricular contractions, are generally reported during extracorporeal shock wave lithotripsy at fixed shock wave delivery in 2 to 20% of patients. These cardiac disturbances rarely pose a serious risk to the healthy patient, and typically resolve spontaneously upon synchronizing the shock waves with the refractory period of the ventricular cycle (i.e., ECG gating) or terminating treatment.

Urinary tract infection: Urinary tract infection (UTI) occurs in 1-7% of patients following extracorporeal shock wave lithotripsy as a result of the release of bacteria from the fragmentation of infected calculi, and infrequently results in pyelonephritis or sepsis. The risk of infectious complications secondary to extracorporeal shock wave lithotripsy can be minimized through the use of prophylactic antibiotics in patients with UTI and infection stones.

Urinary obstruction/steinstrasse: Urinary obstruction occurs in up to 6% of patients following lithotripsy due to stone fragments becoming lodged in the ureter, and may be the result of either a single stone fragment or the accumulation of multiple small stone particles (i.e., steinstrasse). Patients with urinary obstruction typically present with persistent pain, and may be at risk of developing hydronephrosis with subsequent renal failure if the obstruction is not promptly treated. Intervention is necessary if the obstructing fragments do not pass spontaneously.

Skin bruising at shock wave entry site: Skin bruising at the shock wave entry site occasionally occurs after treatment, and typically resolves spontaneously.

Fever (> 38°C): Fever is occasionally reported after lithotripsy, and may be secondary to infection.

Nausea/vomiting: Transient nausea and vomiting are occasionally reported immediately after lithotripsy, and may be associated with either pain or the administration of sedatives or analgesia.

Hematoma (perirenal/intrarenal): Clinically significant intrarenal or perirenal hematomas occur in < 1% of lithotripsy treatments. These patients typically present with severe, chronic flank pain. Although clinically significant hematomas often resolve with conservative management, severe hemorrhage and death have been reported. Management of severe renal hemorrhage includes the administration of blood transfusions, percutaneous drainage, or surgical intervention.

Renal injury: Extracorporeal shock wave lithotripsy procedures have been known to cause damage to the treated kidney. The potential for injury, its long-term significance, and its duration are unknown.

C. Other Labeling Considerations Specific to SWL Systems

To assist manufacturers in the preparation of labeling for extracorporeal shock wave lithotripters, it is recommended that Appendix 2 of this guidance ("SWL Labeling Template") be used as a template for the following sections of the operator's manual: Device Description, Indications and Usage, Contraindications, Warnings and Precautions, Adverse Events, Patient Selection and Treatment, and Safe Radiation Practices.

Additionally, FDA recommends that the labeling of SWL systems include the general and technical description information outlined in consensus standard IEC 60601-2-36, Clause 6. Although not specified in IEC 60601-2-36, FDA believes that the information called for in Clause 6.8.3 should be provided for minimum, typical, and maximum shock wave generator output settings.

D. Labeling Considerations for Mobile/Transportable Configurations

If either mobile or transportable versions of the device are proposed, labeling specific to these device configurations should be prepared and submitted. These additional labeling materials should include:

- a description of how to prepare the device for use after transportation;
- the system evaluation protocol that the user must follow prior to patient treatment to verify that the device has not been damaged during transportation, including verification of the alignment of the localization/stone targeting system with the shock wave focus;
- a description of how to prepare the device for transportation;
- a description of the transportation vehicle; and
- (for mobile versions) a description of the mobile lithotripsy suite.

E. Patient Labeling

Patient labeling is not required for SWL systems. However, if patient labeling is intended to be distributed with the device, it should be submitted in the 510(k) for review. For manufacturers wishing to develop patient labeling, the following items should be considered:

- labeling should be written and formatted so as to be easily read and understood by most patients (i.e., 7th grade reading level);
- it should give readers realistic expectations of the benefits and risks of extracorporeal shock wave lithotripsy treatment, and briefly describe each of the potential complications; and
- it should briefly describe the alternative treatments.

F. Promotional Literature

Any promotional literature regarding the proposed device should be submitted in the 510(k) for review.

10. Training Program

Manufacturers of SWL systems should submit a description of a physician training program within the 510(k). This training program should provide potential users with detailed instructions regarding (1) how to operate the proposed SWL system and (2) the general practices for the safe and effective use of extracorporeal shock wave lithotripters.

11. Other Administrative Requirements

Each 510(k) submission should contain the following administrative items:

- a completed "Indications for Use" form;
- a signed "Truthful and Accurate Statement"; and
- either a "510(k) Summary" or "510(k) Statement."

Information regarding each of the above items is available from DSMA.

12. Device Modifications

Guidance concerning the premarket requirements for device modifications is available in the document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (1/10/97). A copy is available from DSMA or CDRH's Internet address *(http://www.fda.gov/cdrh/ode/510kmod.html)*

Appendix 1: SWL Specifications Sheet

The "Device Description" section of 510(k) should include the following technical information regarding the proposed device (for modifications to existing SWL devices, only the information relevant to the proposed modification is needed):

Device components sold with the SWL system:

Control Console:

Treatment parameters (*check all that apply*):

Range of shock wave generator output settings _____

Shock wave triggering method(s):

Fixed frequency _____

Shock wave frequency (Hz) _____

ECG gating _____

Respiration gating _____

Other user-selectable parameters: _____

Shock Wave Generator:

Shock wave generation method (*check all that apply*):

Electrostatic spark discharge _____

Electromagnetic _____

Piezoelectric _____

Other method: _____

Shock wave focusing method (*check all that apply*):

Reflector _____

Geometry (ellipsoid, parabolic, etc.) _____

Acoustic lens _____

Spherical dish _____

Other method _____

Shock wave generation system geometry:

Distance between the focus and rim of shock wave generator (mm) _____

Aperture angle (°) _____

Aperture diameter (mm) _____

Typical shock wave generator/shock plug longevity (# shocks) _____

Patient coupling method (*check all that apply*):
- Water cushion (rubber membrane) _____
- Open water basin _____
- Water tub _____
- Other method _____

Water System:

Components (*check all that apply*):
- Water circulation system _____
- Reservoir _____
  - Reservoir volume (l) _____
- Degasser _____
- Deionizer _____
- Other components _____

Localization/Imaging System:

Localization/imaging method (*check all that apply; indicate primary/secondary*):
- X-ray:
  - Radiographic film _____
  - Radiographic digital image _____
  - Fluoroscopy _____
  - Other _____
- Ultrasound:
  - Transducer inline with shock wave path _____
  - Transducer mounted on locating arm _____
  - Hand-held transducer _____
  - Other _____
- Other imaging method _____

510(k) number(s) of integral imaging system(s) (if known) _____

Localization accuracy/uncertainty of primary imaging system (mm) _____

Does a user localization accuracy check exist? (*y/n*) _____

Patient Table:

Table type (*check all that apply*):
- Stationary _____
- Manual _____
- Motorized _____

Maximum patient weight (kg) _____

Accessories (*check all that apply*):

ECG monitor	_____
Respiration monitor	_____
Other accessories	_____

Software Description

Microprocessor/Software Control? (*y/n*) _____

Acoustic Output Characteristics:

Shock Wave Characteristics (*the following quantities, as defined in IEC 61846, should be provided for minimum, typical, and maximum shock wave generator output settings*):

		Min/Typical/Max
Peak-positive acoustic pressure (MPa)		___/___/___
Peak-negative acoustic pressure (MPa)		___/___/___
Rise time (ns)		___/___/___
Compressional pulse duration (ns)		___/___/___
Maximum focal width (mm)		___/___/___
Orthogonal focal width (mm)		___/___/___
Focal extent (mm)		___/___/___
Focal volume (cm^3)		___/___/___
Distance between the focus and target location (mm)		___/___/___
Derived focal acoustic pulse energy (mJ)		___/___/___
Derived acoustic pulse energy at specified values of radius R (mJ)	*R1*:	___/___/___
	R2:	___/___/___

Electrical Safety/Electromagnetic Compatibility:

Line Power Requirements (V, Hz) _____

Applicable Standards:

Electrical safety standard(s)	_____
Electromagnetic compatibility standard(s)	_____

Device Configuration

Proposed Device Configurations (*check all that apply*):

Stationary: _____

(Describe room/installation requirements)

Mobile: _____

(Describe site requirements, mobile suite requirements, and truck/trailer specifications)

Transportable: _____

(Describe room/installation requirements and truck/trailer specifications)

Appendix 2: SWL Labeling Template

The operator's manual for the SWL system should include the information listed in the sections below. These sections should be placed in the opening chapter of the operator's manual, and appear in the order listed. Furthermore, the first three sections (i.e., Device Description, Indications and Usage, and Contraindications) should appear on the same page, ideally the first page, of the labeling.

Regular, unitalicized type is reserved for specific language that is recommended for the section (or, in the case of the Indications and Usage section, language that is illustrative of the expected wording). Italicized wording, on the other hand, indicates instructions to the device manufacturer regarding the types of information that should be included.

Caution: Federal law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program.

DEVICE DESCRIPTION

This section should provide the reader with a brief overview of the SWL system, including an identifying description of the device, how the device functions, the major components of the device, and the device's significant physical and performance characteristics. Detailed technical descriptions of the SWL system and its components should be presented later in the operator's manual within a separate section/chapter.

INDICATIONS AND USAGE

The [*device trade name*] is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

CONTRAINDICATIONS

Do not use the [*device trade name*] patients with:

- Confirmed or suspected pregnancy.

- Coagulation abnormalities (as indicated by abnormal prothrombin time, partial thromboplastin time, or bleeding time) or those currently receiving anticoagulants (including aspirin).

- Arterial calcification or vascular aneurysm in the lithotripter's shock wave path.

- Urinary tract obstruction distal to the stone.

- Anatomy which precludes focusing the device at the target stone, such as severe obesity or excessive spinal curvature.

WARNINGS AND PRECAUTIONS

Patient selection

WARNING
Anticoagulants: Patients receiving anticoagulants (including aspirin) should temporarily discontinue such medication prior to extracorporeal shock wave lithotripsy to prevent severe hemorrhage.

CAUTION
Impacted or embedded stones The effectiveness of extracorporeal shock wave lithotripsy may be limited in patients with impacted or embedded stones. Alternative procedures are recommended for these patients.

Staghorn stones: The effectiveness of extracorporeal shock wave lithotripsy may be limited in patients with either staghorn or large (> 20 mm in largest dimension) stones. Alternative procedures are recommended for these patients.

Small ureteral stones Small middle and lower ureteral stones, 4 to 6 mm in largest dimension, are likely to pass spontaneously. Therefore, the risks and benefits of extracorporeal shock wave lithotripsy should be carefully assessed in this patient population.

Pretreatment set-up

WARNING
Cardiac monitoring: Always perform cardiac monitoring during lithotripsy treatment, since the use of extracorporeal shock wave lithotripsy has been reported to cause ventricular cardiac arrhythmias in some individuals. This warning is especially important for patients who may be at risk of cardiac arrhythmia due to a history of cardiac irregularities or heart failure.

Pacemaker or implantable defibrillator To reduce the incidence of malfunction to a pacemaker or implantable defibrillator, the pulse generator should be programmed to a single chamber, non-rate responsive mode (pacemakers) or an inactive mode (implantable defibrillators) prior to lithotripsy, and evaluated for proper function post-treatment. Do not focus the lithotripter's shock wave through or near the pulse generator.

Infected stones: Prophylactic antibiotics should be administered prior to treatment whenever the possibility of stone infection exists. Extracorporeal shock wave lithotripsy treatment of pathogen-harboring calculi could result in systemic infection.

Cardiac disease, immunosuppression, and diabetes mellitus Prophylactic antibiotics should be administered prior to extracorporeal shock wave lithotripsy treatment to patients with cardiac disease (including valvular disease), immunosuppression, and diabetes mellitus, to prevent bacterial and/or subacute endocarditis.

Treatment:

WARNING

Bilateral stones: Do not perform bilateral treatment of kidney stones in a single treatment session, because either bilateral renal injury or total urinary tract obstruction by stone fragments may result. Patients with bilateral kidney stones should be treated using a separate treatment session for each side. In the event of total urinary obstruction, corrective procedures may be needed to assure drainage of urine from the kidney.

Air-filled interfaces in shock wave path Do not apply shock waves to air-filled areas of the body, i.e., intestines or lungs. Shock waves are rapidly dispersed by passage through an air-filled interface, which can cause bleeding and other harmful side effects.

Cardiac arrhythmia during treatment If a patient experiences cardiac arrhythmia during treatment at a fixed shock wave repetition rate, shock wave delivery should either be terminated or switched to an ECG-gated mode (i.e., delivery of the shock wave during the refractory period of the patient's cardiac cycle). As a general practice, patients with a history of cardiac arrhythmia should be treated in the ECG-gated mode. [*If the system is capable of delivering shock waves at a fixed frequency.*]

CAUTION

Renal injury: To reduce the risk of injury to the kidney and surrounding tissues, it is recommended that: (1) the number of shock waves administered during each treatment session be minimized; (2) retreatment to the same kidney/anatomical site occur no sooner than 1 month after the initial treatment; and (3) each kidney/anatomical site be limited to a total of three treatment sessions.

Use of fluoroscopy While fluoroscopy must be used during the procedure, caution should be used to minimize the exposure. [*If fluoroscopic localization is required for use of the device.*]

Electromagnetic interference: If electromagnetic interference between the extracorporeal shock wave lithotripter and nearby electronic equipment is suspected (as evidenced by erratic behavior with either device), it is recommended that their distance be increased until proper operation resumes. If it is necessary to operate an electronic device in close proximity to the lithotripsy system during treatment, the device and the lithotripter should be tested for proper simultaneous operation prior to clinical use.

Post-treatment:

CAUTION
Radiographic follow-up All patients should be followed radiographically after treatment until stone-free or there are no remaining stone fragments which are likely to cause silent obstruction and loss of renal function.

Device maintenance:

CAUTION
Electrical shock hazard Never remove any of the cabinet covers to the system's electronics. The high voltage power supply circuits utilized by extracorporeal shock wave lithotripters use voltages that are capable of causing serious injury or death from electric shock.

ADVERSE EVENTS

Potential adverse events associated with the use of extracorporeal shock wave lithotripsy include those listed below, categorized by frequency and individually described:

Potential Adverse Events of Extracorporeal Shock Wave Lithotripsy

Commonly reported (> 20% of patients)

- Hematuria
- Pain/renal colic
- Skin redness at shock wave entry site

Occasionally reported (1-20% of patients)

- Cardiac arrhythmia
- Urinary tract infection
- Urinary obstruction/steinstrasse
- Skin bruising at shock wave entry site
- Fever (> 38°C)
- Nausea/vomiting

Infrequently reported (< 1% of patients)

- Hematoma (perirenal/intrarenal)
- Renal injury

Hematuria: Hematuria occurs following most treatments, is believed to be secondary to trauma to the renal parenchyma, and usually resolves spontaneously within 24 to 48 hours of treatment.

Pain/renal colic: Pain/renal colic commonly occurs during and immediately after treatment, and typically resolves spontaneously. Temporary pain/renal colic may also occur secondary to the passage of stone fragments, and can be managed with medication.

Skin redness at shock wave entry site: Skin redness at the shock wave entry site commonly occurs during and immediately after treatment, and typically resolves spontaneously.

Cardiac arrhythmia: Cardiac arrhythmias, most commonly premature ventricular contractions, are generally reported during extracorporeal shock wave lithotripsy at fixed shock wave delivery in 2 to 20% of patients. These cardiac disturbances rarely pose a serious risk to the healthy patient, and typically resolve spontaneously upon synchronizing the shock waves with the refractory period of the ventricular cycle (i.e., ECG gating) or terminating treatment.

Urinary tract infection Urinary tract infection (UTI) occurs in 1-7% of patients following extracorporeal shock wave lithotripsy as a result of the release of bacteria from the fragmentation of infected calculi, and infrequently results in pyelonephritis or sepsis. The risk of infectious complications secondary to extracorporeal shock wave lithotripsy can be minimized through the use of prophylactic antibiotics in patients with UTI and infection stones.

Urinary obstruction/steinstrasse Urinary obstruction occurs in up to 6% of patients following lithotripsy due to stone fragments becoming lodged in the ureter, and may be the result of either a single stone fragment or the accumulation of multiple small stone particles (i.e., steinstrasse). Patients with urinary obstruction typically present with persistent pain, and may be at risk of developing hydronephrosis with subsequent renal failure if the obstruction is not promptly treated. Intervention is necessary if the obstructing fragments do not pass spontaneously.

Skin bruising at shock wave entry: Skin bruising at the shock wave entry site occasionally occurs after treatment, and typically resolves spontaneously.

Fever (> 38C): Fever is occasionally reported after lithotripsy, and may be secondary to infection.

Nausea/vomiting: Transient nausea and vomiting are occasionally reported immediately after lithotripsy, and may be associated with either pain or the administration of sedatives or analgesia.

Hematoma (perirenal/intrarenal): Clinically significant intrarenal or perirenal hematomas occur in < 1% of lithotripsy treatments. These patients typically present with severe, chronic flank pain. Although clinically significant hematomas often resolve with conservative management, severe hemorrhage and death have been reported. Management of severe renal hemorrhage includes the administration of blood transfusions, percutaneous drainage, or surgical intervention.

Renal injury: Extracorporeal shock wave lithotripsy procedures have been known to cause damage to the treated kidney. The potential for injury, its long-term significance, and its duration are unknown.

PATIENT SELECTION AND TREATMENT

Specific patient populations:

Children: The safety and effectiveness of this device in the treatment of urolithiasis in children have not been demonstrated. Although children have been treated with shock wave therapy for upper urinary tract stones, experience with lithotripsy in such cases is limited. Studies indicate that there are growth plate disturbances in the epiphyses of developing long bones in rats subjected to shock waves. The significance of this finding to human experience is unknown.

Women of childbearing potential: The treatment of lower ureteral stones should be avoided in women of childbearing potential. The application of shock wave lithotripsy to this patient population could possibly result in irreversible damage to the female reproductive system and to the unborn fetus in the undiagnosed pregnancy.

SAFE RADIATION PRACTICES

[*Only include this section if the SWL system is labeled for x-ray stone localization.*]

This section should present an overview of the practices for the safe use of ionizing radiation. As part of this section, the following information should be conveyed:

- *the importance of using the minimum technique factors and exposure durations necessary for adequate stone imaging and localization;*
- *the maximum technique factors and exposure durations that should be used, as well as an indication of the maximum radiation dosage that would be expected to be delivered to the patient during a single SWL treatment; and*
- *guidelines on how to minimize radiation exposure to the device operator and other health care staff.*