510(k) SUMMARY

Sponsor/Submitter: Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600
Phone: (310) 338-8100
Fax: (310) 410-5519

Contact Person: Crystal Dizol
Regulatory Affairs Associate
Email: cdizol@ksea.com

Date of Submission: September 24, 2007

Device Trade Name: Storz MODULITH® Lithotripter SLX-F2 F180
Common Name: Extracorporeal Shock Wave Lithotripter
Classification Name: Lithotripter, Extracorporeal Shock-Wave, Urological

Regulation Number: 21 CFR 876.5990
Product Code: LNS

Predicate Device(s): Storz MODULITH Lithotripter SLX-F2 (K040476)
Medispec Econolith EM1000 (K063504)

Device Description: The Storz MODULITH® Lithotripter SLX-F2 F180 is an Extracorporeal Shock Wave Lithotripter Device. It generates shock waves that are focused onto a kidney or ureteral stone so that the stone fragments can be passed with the patient’s urine.

Indications for Use: The Storz MODULITH® Lithotripter SLX-F2 F180 is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

Technological Characteristics: The Storz MODULITH® Lithotripter SLX-F2 F180 and its predicate devices generate shock waves using electromagnetically repelled membranes. The shock waves are focused onto the stone by a parabolic reflector dish, and are transferred to the patient’s body via contact with a water-filled rubber cushion.

Summary of Substantial Equivalence: The Storz MODULITH® Lithotripter SLX-F2 F180 is substantially equivalent to the predicate devices since the intended uses and technological characteristics are similar. The minor differences between the Storz MODULITH® Lithotripter SLX-F2 and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function or intended use of the devices.

Att: Substantial Equivalence Table for Storz MODULITH® Lithotripter SLX-F2 F180
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Storz Medical AG</th>
<th>Storz Medical AG</th>
<th>Medispec, Ltd.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade/Proprietary Name</td>
<td>MODULITH® SLX-F2 F180</td>
<td>MODULITH® SLX-F2</td>
<td>Econolith™ EM1000</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>Not Yet Assigned</td>
<td>K040476</td>
<td>K063504</td>
</tr>
<tr>
<td>Shock wave generator</td>
<td>Electromagnetic</td>
<td>Electromagnetic</td>
<td>Electromagnetic</td>
</tr>
<tr>
<td>Diameter of source</td>
<td>390 mm</td>
<td>300 mm</td>
<td>Unavailable</td>
</tr>
<tr>
<td>Treatment depth</td>
<td>180 mm</td>
<td>165 mm</td>
<td>145-175 mm</td>
</tr>
<tr>
<td>Focal size (typical)</td>
<td>F1: 2 x 24 mm</td>
<td>F1: 2 x 20 mm</td>
<td>11 x 175 mm</td>
</tr>
<tr>
<td></td>
<td>F2: 4.7 x 39 mm</td>
<td>F2: 4.8 x 36 mm</td>
<td></td>
</tr>
<tr>
<td>Peak-positive pressure,</td>
<td>F1: 18 – 107</td>
<td>F1: 18 – 107</td>
<td>9.8 – 41.6</td>
</tr>
<tr>
<td>Min/Max (MPa)</td>
<td>F2: 15 – 36</td>
<td>F2: 16 – 44</td>
<td></td>
</tr>
<tr>
<td>Focal energy,</td>
<td>F1: 1.9 – 2.1</td>
<td>F1: 2.2 – 2.5</td>
<td>Unavailable</td>
</tr>
<tr>
<td>Min/Max (MPa)</td>
<td>F2: 3.8 – 4.0</td>
<td>F2: 4.3 – 5.5</td>
<td></td>
</tr>
<tr>
<td>Number of Energy Levels</td>
<td>26</td>
<td>26</td>
<td>Unavailable</td>
</tr>
<tr>
<td>Intended Use</td>
<td>For use in noninvasive fragmentation of urinary calculi in the kidney and upper ureter.</td>
<td>For use in noninvasive fragmentation of urinary calculi in the kidney and upper ureter.</td>
<td>For use in non-invasive fragmentation of upper urinary tract stones, to include urinary stones located in the kidney (renal pelvis and renal calyces) and upper ureter.</td>
</tr>
</tbody>
</table>
Crystal Dizol  
Regulatory Affairs Associate  
Karl Storz Endoscopy-America, Inc.  
600 Corporate Pointe 5th Floor  
Culver City, CA 90230-7600  

Re: K072788  
Trade/Device Name: Storz MODULITH® Lithotripter SLX-F2 F180  
Regulation Number: 21 CFR 876.5990  
Regulation Name: Extracorporeal shock wave lithotripter  
Regulatory Class: Class II  
Product Code: LNS  
Dated: September 24, 2007  
Received: October 1, 2007  

Dear Ms. Dizol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1796, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 876.xxxx</td>
<td>240-276-0115</td>
</tr>
<tr>
<td>21 CFR 884.xxxx</td>
<td>240-276-0115</td>
</tr>
<tr>
<td>21 CFR 892.xxxx</td>
<td>240-276-0120</td>
</tr>
<tr>
<td>Other</td>
<td>240-276-0100</td>
</tr>
</tbody>
</table>

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address [http://www.fda.gov/cdrh/industry/support/index.html](http://www.fda.gov/cdrh/industry/support/index.html).

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
INDICATIONS FOR USE

510(k) Number (if known): K072788

Device Name: Storz MODULITH® Lithotripter SLX-F2 F180

Indications for Use: The Storz MODULITH® Lithotripter SLX-F2 F180 is intended for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

Prescription Use: ✔ AND/OR Over-The-Counter Use: 

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(510(k) Number K072788)