K974796
1 of 2

510(k) Summary

Medispec, Ltd.'s LITHOSPEC™

510(k) Number K_____

MAR 12 1998

Applicant's Name:

Medispec, Ltd.
15200 Shady Grove Rd., Suite 350
Rockville, MD 20850

Contact Person:

Avner Spector
19110 Montgomery Village Ave., Suite 100
Gaithersburg, MD 20879
Telephone: 301-975-0092 Fax: 301-975-1057

Date Prepared:

December xx,1997

Trade Name:

LITHOSPEC™ Intracorporeal Lithotripter

Classification Name:

Bladder Stone Triptor

Classification:

The FDA has classified mechanical lithotriptor as a class II device (product code 78 FGK) and it is reviewed by the Urology and Lithotripsy Devices Branch.

K974796
2 of 2

Predicate Devices:

The LITHOSPEC™ system is substantially equivalent to the EMS SWISS LITHOCLAST LITHOTRIPTER cleared under K951531 and K963285.

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the LITHOSPEC™ complies with IEC 601.1.2, IEC 801.1-801.5, EN 55011, and EN 50081-1.

Indication for Use:

The LITHOSPEC™ Intracorporeal Lithotripter is intended to be used during urological procedures to crush and remove bladder, ureteral and renal stones.

Device Description:

The LITHOSPEC™ is a direct contact intracorporeal lithotripter which fragments bladder, ureteral and renal calculi by utilizing direct endoscopic techniques. The electromechanical technique ensures the delivery of high impact mechanical fragmentation power to the stone while eliminating the possibility of thermal injury.
Four reusable Probes, having diameters: 0.8 mm, 1.0 mm; 1.6 mm, and 2.0 mm, are provided with the system.
The LITHOSPEC™ is operated using standard endoscopic equipment.

Substantial Equivalence:

The LITHOSPEC™ Intracorporeal Lithotripter is substantially equivalent to the EMS SWISS LITHOCLAST LITHOTRIPTER cleared under K951531 and K963285 in respect to intended use, technological characteristics, performance, and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1998

Mr. Avner Spector
President
MEDISPEC LTD.
19110 Montgomery Village Avenue
Suite 100
Gaithersburg, MD 20879

Re: K974796
LITHOSPEC™ Intracorporeal Lithotripter
Dated: December 17, 1997
Received: December 22, 1997
Regulatory Class: III
21 CFR 876.4480/Procode: 78 FFK

Dear Mr. Spector:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K974796

Device Name: LITHOSPEC™ Intracorporeal Lithotripter

Indications for Use: The LITHOSPEC™ Intracorporeal Lithotripter is intended to be used during urological procedures to crush and remove bladder, ureteral and renal stones.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number K974796

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Robert A. Ochling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974796