K040461
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MAY 2 5 2004

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510(K) SUMMARY

[21 CFR section 807.92]

Applicant's Name and Address

Medispec Ltd.
12850 Middlebrook Road, Suite 1
Germantown, MD 20874
Contact: Sheryl D. Skinner
Phone: 301-944-1575
Fax: 301-972-6098

Date of Summary

February 19, 2004

Device Trade Name

Econolith™ E3000

Device Generic Name

Extracorporeal Shock Wave Lithotripter

Classification Name

Class II - Lithotripter, Extracorporeal Shock Wave (Urological) [21 CFR Section 876.5990] / Product Code - LNS

Intended Use

The Econolith™ E3000 is indicated for use in non-invasive fragmentation of upper urinary tract stones between 5 and 20 mm in size.

Predicate Device

HealthTronic's LithoTron Lithotripsy System (P970019)

Device Description

Medispec Ltd.'s Econolith™ E3000 uses shock waves generated outside the patient's body to fragment urinary calculi within either the kidney or upper ureter. The device consists of an electrohydraulic shock wave generator, control panel, and motorized patient table. Although the device does not provide imaging or monitoring functions, it does contain dedicated interfaces for the requisite fluoroscopic imaging and ECG monitoring.

The shock wave generator is a self-contained unit which includes an underwater electrode, a control system, and a high voltage power supply system.

The treatment table is specifically designed for use with the Econolith™ Lithotripter. The table can position the patient in multi-dimensions and also provides access to the patient's lumbar region through removable inserts.

Substantial Equivalence

The Econolith™ E3000 is substantially equivalent to the HealthTronics Lithotron (cleared under PMA# P970019). Both devices are found to be substantially equivalent in respect to the intended use, principle of operations, ancillary equipment, and technological specifications.

Technological Characteristics

All specifications are in compliance with FDA Guidance for the Content of Premarket Notifications (510(k)) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi, August 2000 and all applicable performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2004

Mr. Anil Dhingra
VP and COO
Medispec Ltd.
12850 Middlebrook Rd., Suite 1
GERMANTOWN MD 20874

Re: K040461
Trade/Device Name: Econolith™ E3000, Model 3000 (SW-6)
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shockwave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: May 4, 2004
Received: May 4, 2004

Dear Mr. Dhingra:

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, 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) 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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

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): K040461

Device Name: Econolith ™ E3000

Indications For Use: The Econolith™ E3000 is indicated for use in non-invasive fragmentation of upper urinary tract stones between 5 and 20 mm in size.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040461