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OCT 12 2004

### 510(k) Summary

This summary is being submitted in accordance with the requirements of 21 CFR 807.87.

#### 1. Sponsor information

Name and address: FMD, LLC  
P. O. Box 1500  
Lorton, VA 22199-1500

Contact: Yousry Faragalla, MD  
Phone: 703-880-4642  
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#### 2. Device information

Trade name: Twinheads® TH-103 Extracorporeal Shock Wave Lithotripter  
Common name: Extracorporeal shock wave lithotripter  
CFR Number: 21 CFR 876.5990 – Extracorporeal shock wave lithotripter  
Product code: 78 LNS  
Regulatory Class: Class II (special controls)

#### 3. Substantial Equivalence

The Twinheads® TH-103 ESWL is substantially equivalent to predicate legally marketed device Twinheads® TH-101 ESWL (K030346)

#### 4. Device description

The Twinheads® TH-103 ESWL is a spark gap dual head shock wave lithotripter for the fragmentation of kidney and ureteral calculi. The Twinheads® TH-103 delivers a pair of shock waves, which are separated from each other by a certain delay time, with perpendicular trajectories and overlapping focal zones. The pulse pairs or twin shocks are aligned with the calculi or stone utilizing legally marketed C-arm fluoroscopy system via two orientations. Also included is an accurate motorized table with carbon fiber top.

#### 5. Intended use

The Twinheads® TH-103 Extracorporeal Shock Wave Lithotripter is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

#### 6. Technological characteristics

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The Twinheads® TH-103 ESWL is a modification of Twinheads® TH-101 ESWL And has the same fundamental scientific technology and intended use.

FMD, LLC.

Twinheads® TH-103 ESWL  
Special 510(k) Premarket Notification

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**7. Clinical study**

No clinical studies were performed.

**1. Conclusion**

The Twinheads® TH-103 Extracorporeal Shock Wave Lithotripter is a modification and substantially equivalent to its predicate legally marketed device and conforms to the requirements of FDA for a special 510(k) submission being a minor modification which does not change the fundamental scientific technology and intended use.



OCT 12 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Yousry Faragalla, M.D.  
President  
FMD, LLC  
P.O. Box 1500  
LORTON VA 22199-1500

Re: K042561  
Trade/Device Name: Twinheads® TH-103 Extracorporeal Shock Wave Lithotripter  
Regulation Number: 21 CFR §876.5990  
Regulation Name: Extracorporeal shock wave lithotripter  
Regulatory Class: II  
Product Code: 78 LNS  
Dated: September 17, 2004  
Received: September 24, 2004

Dear Dr. Faragalla:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.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 Statement**

510(k) Number (if known): K042561

Device Name: Twinheads® TH-103 Extracorporeal Shock Wave Lithotripter

*Indication for Use:*

The Twinheads® TH-103 Extracorporeal Shock Wave Lithotripter is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-counter Use \_\_\_\_\_

Nancy C Brogden  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K042561