MAY 1 6 2002

K020956

Premarket Notification (510k) Summary

Microtek Medical, Inc.
512 Lehmberg Road
Columbus, Mississippi 39702

Telephone: 662-327-1863

Contact Person: Thomas Bonner
Date compiled: March 15, 2002

MICROTEK MEDICAL, inc.

Premarket Summary

Device Name

Proprietary name: VivoSonic™
Common name: In vivo biocompatible, sterile medical diagnostic ultrasound imaging coupling media.

Establishment Registration Number: 1043582 (Microtek Medical, Inc.)

Classification: II

Statement of Substantial Equivalence

VivoSonic™ is equivalent in ultrasound imaging coupling performance to:

1. Aquasonic 100 sterile (Parker Laboratories, Inc.)
2. Ultra/Phonic sterile (Pharmaceutical Innovations)
3. Natural Image (Sontotech, Inc.)

Description of Device

VivoSonic™ is an in vivo biocompatible sterile ultrasound couplant and lubricant that couples or conducts ultrasound between the body and the ultrasound transducer and electronics.

The VivoSonic™ formulation is in vivo biocompatible with tissue and body fluids and is recognized as safe for oral administration (1)

Intended Use

VivoSonic™ will be used during invasive medical diagnostic ultrasound imaging to couple sound waves between patient and medical imaging electronics and to lubricate the insertion and passage of imaging devices, such as ultrasound transducers and endoscopes.

VivoSonic™ is intended for use in conjunction with transcutaneous ultrasound image guided biopsy and aspiration, intraoperative ultrasound imaging, endocavity ultrasound imaging and opthalmic ultrasound imaging.

VivoSonic™ is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures which currently use and ultrasound coupling gel or fluid alone or in combination with a latex, non-latex, polyurethane or polyethylene transducer cover where sterility and/or in vivo biocompatibility are required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2002

Mr. Thomas B. Bonner, Jr.
Vice President, Regulatory
Affairs/Quality Assurance
MICROTEK Medical, Inc.
512 Lehmberg Road
COLUMBUS MS 39702

Re: K020956
Trade/Device Name: VivoSonic™ Diagnostic Ultrasound Imaging Coupling Media
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic transducer
Regulatory Class: II
Product Code: 90 MUI
Dated: March 15, 2002
Received: March 25, 2002

Dear Mr. Bonner:

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.

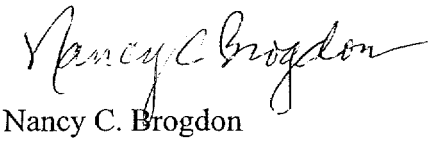
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

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" (21 CFR Part 807.97). 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
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

Device Name: Microtek Medical, Inc. VivoSonic Diagnostic Ultrasound Imaging Coupling Media

Indications for Use Statement:

VivoSonic Media is used during invasive medical diagnostic ultrasound imaging to couple sound waves between the patient and the medical imaging electronics, and to lubricate the insertion and passage of imaging devices.

VivoSonic Media is used in conjunction with transcutaneous ultrasound imaging guided biopsy and apsiration, intraoperative ultrasound imaging, endocavity ultrasound imaging, and opthalmic ultrasound imaging.

VivoSonic Media is intended for use in all diagnostic ultrasound procedures which currently use an ultrasound gel or fluid alone or in combination with a latex, non-latex, polyurethane or polyethylene transducer cover where sterility and vivo biocompatibility are required.

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 Cardiovascular, Respiratory, And Neurological Devices~~

510(k) Number _____

Prescription Use ✓ or Over-The-Counter Use _____
(per 21CFR 801.109)

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020956