Ron-Tech Medical LTD

JAN 9 2004

510(k) Summary:

SafeTChoice™ Transvaginal Ultrasound Probe Holder System

Date submitted: August 15, 2003

Company Name:

Ron-Tech Medical Ltd.

Contact Person: Doron Kilchevsky
CEO

Telephone: +972-9-957-8803
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Trade Name: SafeTChoice™ Transvaginal Ultrasound Probe Holder System

Classification name: Accessory to an ultrasound transducer

Classification: HDC/ITX

Predicate Device:

Transvaginal Ultrasound Probe Holder device, Ron-Tech Medical Ltd. Israel, cleared under 510(k) no. K992071

Description of the device:

The SafeTChoice™ Transvaginal Ultrasound Probe Holder System is an accessory used in conjunction with a transvaginal ultrasound transducer. The device is intended to hold and secure the ultrasound transducer in place on a uterine tenaculum, while performing the sonographic procedure. The configuration of the device allows the physician to manipulate the ultrasound transducer with one hand, thus freeing the other hand to perform the required procedure.

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The SafeTChoice™ Transvaginal Ultrasound Probe Holder System consists of a reusable uterine tenaculum with an adaptor bar, a sterile, disposable adaptor and a disposable probe connector.

Indications for Use:

The SafeTChoice™ Transvaginal Ultrasound Probe Holder System is an accessory intended for use in conjunction with a transvaginal ultrasound transducer. The SafeTChoice™ Transvaginal Ultrasound Probe Holder System is intended to seize and hold the cervix and to hold and secure an ultrasound transducer in place, while performing sonographic procedures.

Substantial Equivalence:

The SafeTChoice™ Transvaginal Ultrasound Probe Holder System has the same intended use and the same principle of operation as the Transvaginal Ultrasound Probe Holder device, cleared under 510(k) no. K9992071.

Conclusion:

The evaluation of the SafeTChoice™ Transvaginal Ultrasound Probe Holder System does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 9 2004

Ms. Doron Kilchevsky
CEO
Ron-Tech Medical, Ltd.
26 Hasivim St. Kiryat Matalon
Petach-Tikva 49170
ISRAEL

Re: K032585
Trade/Device Name: Transvaginal Ultrasound Probe Holder System
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Product Code: 85 HDC
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: 90 ITX
Regulatory Class: II
Dated: November 26, 2003
Received: December 12, 2003

Dear Ms. Kilchevsky:

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): K032585

Device Name: SafeTChoice™ Transvaginal Ultrasound Probe Holder System

Indications for Use: The SafeTChoice™ Transvaginal Ultrasound Probe Holder System is an accessory intended for use in conjunction with a transvaginal ultrasound transducer. The SafeTChoice™ Transvaginal Ultrasound Probe Holder System is intended to seize and hold the cervix and to hold and secure an ultrasound transducer in place, while performing sonographic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE):

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

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Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032585