K032793

OCT - 9 2003

510(k) Summary

US-100 Ultrasound Therapy Unit

Common/Classification Name: Ultrasonic Diathermy Device, 21 CFR 890.5300

Ito Company, Ltd.
3-3-3 Toyotama-Minami
Nerima-Ku
Tokyo 176-8605, Japan

Contact: K. Sunayama, Prepared:September 5, 2003

A. LEGALLY MARKETED PREDICATE DEVICES

The **US-100 Ultrasound Therapy Unit** is substantially equivalent to the ultrasound section of the Sonicator Plus 992 (K984142) by Mettler.

B. DEVICE DESCRIPTION

The **US-100 Ultrasound Therapy Unit** consists of a main unit and two applicators. The device may be operated in continuous or pulsed modes. The **US-100** has an output power of 8 W and operates at 0.8 MHz. It is supplied with one applicator, and another smaller applicator is available as an option.

The device has an LCD screen that serves as the interface with the user to specify options, provide messages, and display parameters.

C. INTENDED USE

The **US-100** is indicated for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions, including relief of pain, muscle spasms, and joint contractures.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **US-100 Ultrasound Therapy Unit** is a medical device, and it has very similar indications for use as the legally marketed predicate device. The differences do not change the intended therapeutic effect. The **US-100 Ultrasound Therapy Unit** has the same technological characteristics as the predicate device. For a few characteristics, performance data were provided, which demonstrate equivalence. This premarket notification

to assure substantial equivalence except for a few of the characteristics where performance testing was carried out (e.g., electrical safety, EMC).

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same as those of the predicate device and other ultrasound diathermy devices.

F. TESTING

Performance testing carried out by Ito Co, Ltd. on the **US-100** addressed the following issues:

(1) Electrical Safety;

(2) Electromagnetic Emissions;

(3) Various Safety and Integrity Issues, and

(4) Performance Standard of 21 CFR 1050.

G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Ito Company, Ltd.
C/o T. Whit Athey, Ph.D.
Senior Consultant
The Health Policy Resources Group, LLC
2305 Gold Mine Road, Suite 200
Brookeville, MD 20833-2233

Re: K032793
Trade/Device Name: US-100 Portable Ultrasound Therapy Unit
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Regulatory Class: II
Product Code: IMI
Dated: September 8, 2003
Received: September 9, 2003

Dear Dr. Athey,

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.

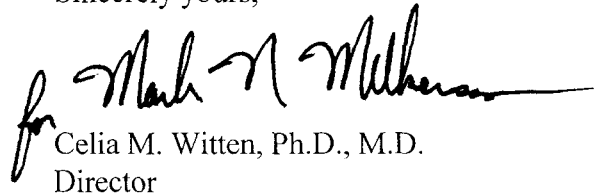
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-1308. 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 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K032793

Device Name: US-100 Ultrasound Therapy Unit

Indications For Use:

The **US-100** is indicated for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions, including relief of pain, muscle spasms, and joint contractures.

(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)

for Mark N Milhern
(Division Sign-Off)
Division of General. Restorative
and Neurological Devices

510(k) Number K032793