K970131

510(k) Summary

JUN 16 1997

ORTHOSONICS DUO-SON ULTRASOUND DIATHERMY DEVICE

Common/Classification Name: Ultrasonic diathermy
21 CFR 890.5300

Sponsor: Orthosonics, Ltd.
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UK
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Contact: Dr. Michael J. R. Young

Prepared: January 14, 1997

A. LEGALLY MARKETED PREDICATE DEVICES

The Orthosonics Duo-Son Ultrasound Diathermy Device is substantially equivalent to the Mettler Model ME-720 (K883228).

B. DEVICE DESCRIPTION

The **Orthosonics Duo-Son Ultrasound Diathermy Device** consists of a two-channel power module which generates the ultrasonic energy and provides overall control of the device, and a handpiece with cable. The applicator design allows the simultaneous delivery of ultrasonic energy to tissue at two frequencies, 1 MHz and 45 kHz.

C. INTENDED USE

The **Orthosonics Duo-Son Ultrasound Diathermy Device** is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures.

D. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Duo-Son device are the same as those of the predicate devices.

E. TESTING

Orthosonics carried out testing to address the following issues:

(1) electrical safety,

(2) electromagnetic compatibility,

(3) temperature rise in a phantom during Duo-Son procedures,

(4) temperature rise in a phantom using the predicate device, and

(5) compliance with 21 CFR 1050.

The results from all of these tests supported the safety and effectiveness of the Orthosonics Duo-Son Ultrasonic Diathermy Device and demonstrate that it is substantially equivalent to the predicate devices.

F. CONCLUSIONS

The Orthosonics Duo-Son device has the *same* intended use and target population as the predicate devices. Orthosonics has demonstrated through its performance tests on the Duo-Son device and its comparison of Duo-Son characteristics with those of the predicate device that the Duo-Son device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

T. Whit Athey, Ph.D.
Senior Consultant
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

JUN 16 1997

Re: K970131
Orthosonics Duo-Sun Ultrasound Diathermy Device
Regulatory Class: II
Product Code: IMI
Dated: May 14, 1997
Received: May 14, 1997

Dear Dr. Athey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **Orthosonics Duo-Son Ultrasound Diathermy Device**

Indications For Use:

The **Orthosonics Duo-Son Ultrasound Diathermy Device** is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970131

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)