K991613
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DEC - 8 2000

STARBENE
510K NOTIFICATION
SW ULTRASOUND

510(k) SUMMARY
(As required by 210 CFR 807.92)

Trade Name :	SW ULTRASOUND
Common / Classification Name :	Ultrasonic Diathermy
Marketed by:	STARBENE David Luque 519 5000- Cordoba Argentina T.E: 54-351-4240051 FAX: 54-351-4240052
Dated Prepared : Additional Information :	April 23rd , 1999 September 17TH , 1999
Contact:	Miss Judith Niztzschmamn International Regulations Department

A- LEGALLY MARKETED PREDICATE DEVICE

The SW ULTRASOUND LINE equipment is substantially equivalent to the following devices marketed:

DEVICE	K NUMBER
1- DYNATRON 125	K961250

B- DEVICE DESCRIPTION

The SW Ultrasound Line is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain , muscle spasms, and joint contractures , but not for the treatment of malignancies .

C- INTENDED USE

The SW Ultrasound Line is intended for use in applying therapeutic deep heat for selected medical conditions.

INDICATIONS FOR USE

INDICATIONS FOR ULTRASOUND USE

Ultrasound therapy is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures , but not for the treatment of malignancies (21 CFR 890.5300)

D- TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the SW Ultrasound device are the same as those of the predicate device.

E- TESTING

Starbene carried out testing to address the following issues

1- Electrical safety
2- Electromagnetic compatibility
3- Temperature rise in a phantom during SW Ultrasound procedures
4- Temperature rise in a phantom using the predicate devices
5- Compliance with the 21 CFR 1050.1

E- CONCLUSIONS

The SW Ultrasound Line has the same intended use and target population as the predicate device.
Starbene has demonstrated through its performance tests on the SW Ultrasound Line equipment and its comparison with those of the predicate device that the SW Ultrasound 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

DEC - 8 2000

Ms. Judith Niztzschmamn
STARBENE
International Regulations Department
David Luque 519
Cordoba, Pvcia, Cordoba,
Argentina

Re: K991613
Trade Name: SW Ultrsound, Models 331, 311, 333
Regulatory Class: II
Product Code: IMI
Dated: September 15, 2000
Received: September 22, 2000

Dear Ms. Judith Niztzschmamn:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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,

for Mark N Melkerson

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

510(k) Number (if known) K991613

Device Name: SW ULTRASOUND

Indications For Use:

IS A THERAPEUTICAL ULTRASONIC DIATHERMY DEVICE FOR PROFESSIONAL USE TO APPLY THERAPEUTIC DEEP HEAT FOR SELECTED MEDICAL CONDITIONS .

(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 K991613

Prescription Use ___ OR Over-The-Counter Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)