



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 22 2002

Mr. Dave Toman  
Metron Medical Australia Pty. Ltd.  
57 Aster Avenue  
(P.O. Box 2164)  
Carrum Downs  
Victoria, Australia 3201

Re: K020119

Trade/Device Name: Vectorsonic Model VU-200  
Regulation Number: 21 CFR 890.5860  
Regulation Name: Ultrasound and muscle simulator  
Regulatory Class: Class II  
Product Code: IMG  
Dated: April 17, 2002  
Received: April 23, 2002

Dear Mr. Toman:

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.

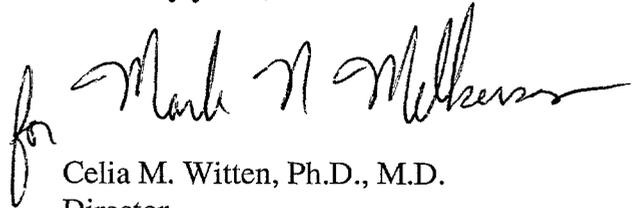
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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)

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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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-. 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). 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,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

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): K020119

DEVICE NAME: Vectorsonic Model VU 200

INDICATIONS FOR USE:

The indications for use for the interferential therapy are:

1. Relaxation of muscle spasm;
2. Prevention or retardation of disuse atrophy;
3. Increasing local blood flow;
4. Muscle re-education;
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion.

The indications for use for the ultrasound therapy are:

1. Relief or reduction of pain;
2. Reduction of muscle spasm;
3. Joint contracture; and
4. Local increase in circulation.

The indication for use for the combined therapy is:

1. Reduction of muscle spasm.

*for Mark H. Miller*  
 (Division Sign-Off)  
 Division of General, Restorative  
 and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE) 510(k) Number K020119

Prescription Use    
 (Per 21 CFR 801.109)

OR

Over-The-Counter-Use    
 (Optional Format 1-2-96)