DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

Orthosonix, Incorporated
C/O Mr. Russell Pagano
615 7th St NE, 1st Floor
Washington, DC 20002

Re: K013094
Trade/Device Name: Orthosonix Energex ®
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: NHH
Dated: September 14, 2001
Received: September 17, 2001

Dear Mr. Pagano:

This letter corrects our substantially equivalent letter of December 14, 2001.

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 (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 continue 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013094

Indication for Use Statement

510(k) Number (if known): _____

Device Name: Orthosonix Energex®

Indication for Use:

The Energex is indicated for use for the temporary relief of chronic temporomandibular joint (TMJ) pain.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013094

DEC 1 4 2001

K013094

510(k) Summary

Orthosonix, Inc. Energex®

1. Sponsor

Orthosonix
180 Old Tappan Road
Old Tappan, New Jersey 07675

Contact Person: Thomas Fagan
President

2. Device Name

Classification Name: Shortwave diathermy device

Proprietary Name: Orthosonix Energex®

3. Indications for Use

The Energex is indicated for use for the temporary relief of chronic temporomandibular joint (TMJ) pain.

4. Device Description

The Energex is a therapeutic medical device that delivers pulsed radio-frequency energy to tissue as indicated for the relief of chronic TMJ pain.

5. Basis for Substantial Equivalence

The Energex is substantially equivalent to shortwave diathermy devices that are also indicated for the relief of joint pain. This equivalence was shown through bench, animal and clinical data submitted in the 510(k).