

JUN 6 2002

510(k) Summary

K02/500  
page 1 of 3

Orthosonics OSCAR OE3000

Common/Classification Name: Bone Cement Removal System,  
**888.4580** [REDACTED], Product Code LZV

Orthosonics, Ltd.  
Bremridge House  
Ashburton  
Devon TQ137JX  
UK

Contact: Michael J. R. Young, Ph.D., Prepared: May 7, 2002

**A. LEGALLY MARKETED PREDICATE DEVICES**

Since this premarket submission is for a device modification, obviously the currently marketed version of the **Orthosonics OSCAR System for Cemented Arthroplasty Revision** will serve as one predicate device (K961725).

The laparoscope and optical coupler are currently marketed devices from Precision Optics of Gardner, MA. These devices were cleared as K914084 on January 22, 1992 and K903458 on October 19, 1990.

In addition, the Cement Removal/Extraction System manufactured by Stryker Instruments (K961101) includes an accessory that in terms of hardware and function is very similar to the impact hammer accessory that is also described in the present submission.

**B. DEVICE DESCRIPTION**

The currently marketed **Orthosonics OSCAR Ultrasonic Cement Removal System** consists of a power module which generates the ultrasonic energy and provides overall control of the device, a handpiece, and a set of cement removal probes.

00033

The primary change to the system is the addition of a laparoscopic video system, which can aid the clinician in examining the inside of the bone that is having its glue removed. This part of the system would only be used when the ultrasound-powered probes are not being used. The laparoscope and optical coupler are currently marketed medical devices. In order to make room for the video module in the main system unit of the **OE3000**, the ultrasonic power modules were reduced in physical size.

In addition, the currently marketed device now has an optional accessory that was added to the system via a letter-to-file, without filing a new 510(k). The change involves adding a "slap hammer" that can be attached to an "extraction" probe, to aid in removal of a PMMA cement plug that is NOT firmly bonded to the endosteal interface. The Extraction Probe to be used with the slap hammer is a modified version of the piercer probe that was cleared with the original 510(k). Even though an accessory to a Class II device would normally be itself a Class II device that requires a 510(k), in this case the accessory, the slap hammer, is separately classified as a Class I device (Orthopedic Manual Surgical Instrument, 21 CFR 888.4540), and so did not require a 510(k).

**C. INTENDED USE**

The **Orthosonics OSCAR OE3000** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

**D. SUBSTANTIAL EQUIVALENCE SUMMARY**

The modified **OE3000** is a medical device, and it has the same indications for use and the same target population as the legally marketed predicate devices. The modified **OE3000** has the same technological characteristics as the predicate devices. Those characteristics are described herein in sufficient detail to assure that the modified **OE3000** is substantially equivalent to the predicate device.

**E. TECHNOLOGICAL CHARACTERISTICS**

The technological characteristics of the **OSCAR OE3000** are exactly the same as those of the predicate devices.

*K01502 page 2 of 3*

**00034**

**F. TESTING**

The OSCAR OE3000 was tested to the requirements of the following standards:

EN60601-1 General Requirements for Safety  
EN60601-1-1 Electrical Safety  
EN60601-1-2 EMC

**G. CONCLUSIONS**

This pre-market submission has demonstrated Substantial Equivalence<sup>1</sup> as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

---

<sup>1</sup> The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(l)(1) of the Federal Food, Drug, and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 6 2002

Orthosonics, Ltd.  
c/o T. Whit Athey, Ph.D.  
Senior Consultant  
Health Policy Resources Group, LLC  
2305 Gold Mine Road, Suite 200  
Brookeville, Maryland 20833

Re: K021502  
Trade Name: OSCAR OE3000  
Regulation Number: 21 CFR 888.4580  
Regulation Name: Sonic surgical instrument and accessories/attachments  
Regulatory Class: II  
Product Code: LZV  
Dated: May 8, 2002  
Received: May 9, 2002

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket 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) 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.

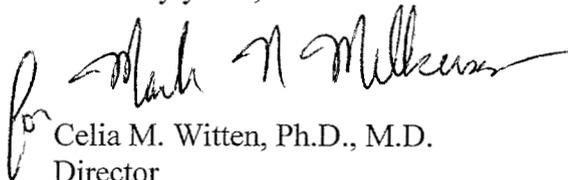
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – T. Whit Athey, Ph.D.

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 and additionally 21 CFR Part 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" (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 "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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

page 1 of 1

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K021502

Device Name: OSCAR OE3000

Indications For Use:

The **OE3000** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

*for Mark N. Milburn*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K021502