SEP 22 2003

K031280 1/1

BIOMET

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Ultra-Drive® 3

Common or Usual Name: Ultrasonic Surgical Instrument

Classification Name: Instrument, Surgical, Sonic and Accessories/Attachments (21 C.F.R. 888.4580)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: The Ultra-Drive® 3 system is substantially equivalent to the System 10, Model 100 Surgical System for Orthopedic Use, cleared through 510(k) K900003.

Device Description: The Ultra-Drive® 3 consists of a control console, a footswitch, a handpiece with associated cables and connecting tubing, a variety of tool tips and other associated accessories.

The system converts standard electrical power (120/240V) into electrical energy at 40 kHz. The high frequency electrical energy produced by the generator is sent through a cable to a transducer that changes the electrical energy into longitudinal 40kHz vibrations. The ultrasonic vibrations are then transmitted to the tool tip that is supplied to the bone or bone cement which is to be removed.

Intended Use: Cutting and removal of bone and acrylic bone cement in orthopedic applications

Summary of Technologies: The materials and operating principles of the Ultra-Drive® 3 system are similar to that of the predicate.

Clinical and Non-Clinical Testing: None provided

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Warsaw, IN 46581-0587

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56 E. Bell Drive
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2003

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K031280
Trade/Device Name: Ultra-Drive 3
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic Surgical Instrument and Accessories/Attachments
Regulatory Class: II
Product Code: JXJ
Dated: July 8, 2003
Received: July 9, 2003

Dear: Ms. Beres:

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) 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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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): K031280

Device Name: Ultra-Drive® 3

Indications For Use:

Cutting and removal of bone and acrylic bone cement in orthopedic applications.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031280

(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

(Optional Format 1-2-96)