K051656

OCT 25 2005

510 (k) SUMMARY

Submitter	*Contact*
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Date of Summary: June 16, 2005

Common Name: Drill Sleeve Caps, Drills, Obturators, Sizers, Handle, Ruler, Drill Sleeves, Sterilization Tray, Delivery Device with Measuring Tamp

Proprietary Name: OCT (Osteochondral Transplant) Comprehensive System

Device Classification: Orthopedic Manual Surgical Instruments, Template Surgical Instruments Motors Accessories

510(k) Number:

Description of Device: The OCT (Osteochondral Transplant) Comprehensive System is a kit composed of several orthopedic surgical instruments. These instruments include Drill Sleeve Cap, Drills, Toothed Core Sleeve and Plunger, Obturators, Sizers, Drill Handle, Ruler and Drill Sleeves and Sterilization Tray. All instruments are composed of stainless steel and/or injection molded plastic. The instruments range in size from 3 to 11 mm.

Intended Use: The OCT (Osteochondral Transplant) Comprehensive System is indicated for arthroscopic (knee and ankle) and open osteochondral grafting for the treatment of osteochondral (cartilage) defects.

Substantial Equivalence: The OCT (Osteochondral Transplant) Comprehensive System is substantially equivalent in design, function an performance to the Acufex® MosaicPlasty™ Comprehensive System cleared as K964215 on December 20, 1996.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2005

Gabriele G. Niederauer, Ph.D.
Director of Research and Development
OsteoBiologics, Inc.
12500 Network, Suite 112
San Antonio, Texas 78249-3300

Re: K051656
Trade/Device Name: OCT (Osteochondral Transplant) Comprehensive System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: October 14, 2005
Received: October 17, 2005

Dear Dr. Niederauer:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.4 Indications for Use (Form)

INDICATIONS FOR USE

510(k) Number (if known): K051656

Device Name: OCT (Osteochondral Transplant) Comprehensive System

Indications For Use:
The OCT (Osteochondral Transplant) Comprehensive System is indicated for arthroscopic (knee and ankle) and open osteochondral grafting for the treatment of osteochondral (cartilage) defects.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brown

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

510(k) Number K051656