APR 1 1 2005

K050490

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OSMOSYS Bone Substitute
510(k) Summary
April 4, 2005

Submitter	MEDICREA TECHNOLOGIES ZI Chef de Baie 17000 La Rochelle France
Contact person	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199
Trade Name	OSMOSYS Calcium Phosphate Ceramic Bone Filler
Common name	Bone void filler
Classification name	Filler, calcium sulfate, preformed pellets Class II per 21 CFR section 888.3045
Product Code	MQV
Equivalent Device	Calcigen (K030178) (Biomet - Warsaw, IN) Mastergraft Resorbable Ceramic (K020986) (Medtronic Sofamor Danek - Memphis,TN).

Device Description

OSMOSYS is a synthetic bone substitute composed of a mixture of hydroxyapatite (HA) and tricalcium phosphate (TCP). The resulting product is a biphasic macro-porous bio-ceramic designed to fill bony void gaps of the skeletal system (i.e., the extremities, spine and pelvis) resulting from surgery or trauma that are not intrinsic to the stability of the bony structure. Analysis by pycnometry reveals the presence of pores representing on average 70% of the volume of the material. The pores are between 300µm and 500µm, correlating well with the values from optic microscopy. OSMOSYS is available in the form of irregular granules (2-3 mm) and sticks (5x5x20 mm).

OSMOSYS is in conformity with the specifications of ASTM F1088-1987 and ASTM F1185-2003.

Intended Use

OSMOSYS is intended for use as a bone void filler to fill bony void gaps of the skeletal system (i.e. the extremities, spine and pelvis) resulting from surgery or trauma that are not intrinsic to the stability of the bony structure. OSMOSYS is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. Following placement in the bony voids or gap, OSMOSYS resorbs and is replaced with bone during the healing process.

Summary Nonclinical Tests

OSMOSYS is similar to the predicate device in terms of composition, porosity, pore size, and resorption.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2005

MEDICREA TECHNOLOGIES
C/o Mr. J.D. Webb
OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K050490
Trade/Device Name: OSMOSYS Calcium Phosphate Ceramic Bone Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: February 21, 2005
Received: March 02, 2005

Dear Mr. Webb:

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) 276-0120 . 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,

for Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050490

Device Name: OSMOSYS Calcium Phosphate Ceramic Bone Filler

Indications for Use:

OSMOSYS is intended for use as a bone void filler to fill bony void gaps of the skeletal system (i.e. the extremities, spine and pelvis) resulting from surgery or trauma that are not intrinsic to the stability of the bony structure. OSMOSYS is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. Following placement in the bony voids or gap, OSMOSYS resorbs and is replaced with bone during the healing process.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General [illegible]
and Neurological [illegible]

510(k) Number K050490