2 510(k) Summary [as required by 21 CFR 807.92(c)]

Submitter's Name / Contact Person

CERAbio, LLC
Technology Center
N4660 1165th St.
Prescott, WI 54021-7644

Contact
James J. Cassidy, President

General Information

Trade Name	Apatight™–HA Bone Graft Substitute
Common / Usual Name	Bone Void Filler, Bone Graft Substitute
Classification Name	Filler, Calcium Sulfate Preformed Pellets
Equivalent Devices	Pro Osteon 500R Resorbable Bone Graft Substitute (Interpore Cross, K990131, K980817)

Device Description

Apatight–HA Bone Graft Substitute is a porous hydroxyapatite bone graft substitute for the repair of bony defects. It is an osteoconductive porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. The implant is provided sterile in block and granular forms. Apatight–HA Bone Graft Substitute guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When Apatight–HA Bone Graft Substitute is placed in direct contact with viable host bone, new bone grows in apposition to the surfaces of the implant, filling the pores with new bone during the healing process. The product is completely incorporated into the newly formed bone.

Intended Use / Indications

Apatight–HA Bone Graft Substitute is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Apatight–HA is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product resorbs and is replaced with bone during the healing process.

Substantial Equivalence Comparison

Apatight–HA was shown by analysis of available information to be identical in intended use and equivalent in materials and configuration to the predicate device. The material also satisfies an ASTM standard for implantable hydroxyapatite. Results of performance testing in an animal model showed that the device was well-tolerated and completely integrated into the defect site. The interconnected porosity of the Apatight–HA implants was completely filled with new bone at the follow-up time points and there were no signs of inflammation or infection in any Apatight–HA treated animal. The information presented demonstrated that the Apatight–HA Bone Graft Substitute is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2002

James J. Cassidy, Ph.D.
President
CERAbio, LLC
Technology Center
N4660 1165th St.
Prescott, Wisconsin 54021-7644

Re: K013960
Trade Name: Apatight-HA Bone Graft Substitute
Regulatory Class: unclassified
Product Code: MQV
Dated: March 21, 2002
Received: March 22, 2002

Dear Dr. Cassidy:

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.

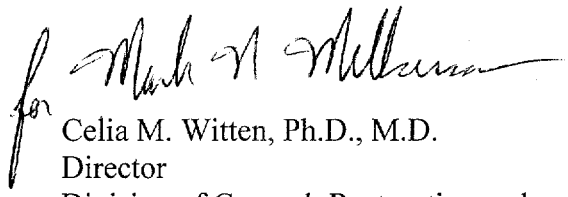
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013960

Device Name: Apatight™ – HA Bone Graft Substitute

Indications for Use:

Apatight–HA Bone Graft Substitute is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Apatight–HA is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product resorbs and is replaced with bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhorn

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

510(k) Number K013960