K120602

MAR 2 3 2012

510(k) SUMMARY
Apaceram™ Bone Void Filler

Submitter Name:	HOYA Corporation PENTAX New Ceramics Division
Submitter Address:	2-7-5 Naka-Ochiai, Shinjuku-ku, Tokyo 161-8525 JAPAN
	Manufacturing Site: PENTAX Mashiko Factory: 858 Hanawa, Mashiko-machi, Haga-gun, Tochigi 321-4292 Japan
Contact Person:	Nobuyuki Asaoka
	International Sales Group New Ceramics Division
Phone Number:	813-5840-6141
Fax Number:	813-5840-6143
Date Prepared:	February 27, 2012
Device Trade Name:	Apaceram™ Bone Graft Substitute
Device Common Name:	Synthetic, porous hydroxylapatite
Classification Number:	21 CFR 888.3045
Classification Name:	Resorbable calcium salt bone void filler
Product Code:	MQV
Predicate Devices:	K071912, Apaceram™ Bone Graft Substitute, Pentax Corp.
Statement of Intended Use:	Apaceram™ Bone Graft Substitute is a synthetic hydroxyapatite provided in several particulate and shaped sizes. It is intended for use as a bone void filler for bony voids, gaps, or defects that are not intrinsic to the stability of the bony structure. Apaceram™ is intended to be placed into bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine, or pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. It also can be used with autograft as a bone graft extender. Apaceram™ is resorbed and replaced with bone during the healing process.
Device Description:	Apaceram™ is a hydroxyapatite osteoconductive bone void filler. It is available in four types: AX, B, G, and R, which vary in porosity, shape and sizes. Apaceram™ is provided sterile for single patient use.
Technological Characteristics and Testing:	Apaceram™ is composed of calcium salts, is osteoconductive, and provides an interconnected, highly porous scaffold environment for new bone ingrowth. The safety, performance and biocompatibility testing were submitted in the original Apaceram™ 510(k).
Substantial Equivalence:	The Apaceram™ Bone Graft Substitute is identical to the predicate device. The purpose of this 510(k) is to reflect the change in ownership of Apaceram™ from Pentax Corporation to HOYA Corporation PENTAX New Ceramics Division.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hoya Corporation
PENTAX New Ceramics Division
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5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

MAR 2 3 2012

Re: K120602
Trade/Device Name: Apaceram™ Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: February 27, 2012
Received: February 28, 2012

Dear Ms. Trisler

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K120602

Device Name: Apaceram™ Bone Graft Substitute

Indications for Use:

Apaceram™ Bone Graft Substitute is a synthetic hydroxyapatite provided in several particulate and shaped sizes. It is intended for use as a bone void filler for bony voids, gaps, or defects that are not intrinsic to the stability of the bony structure. Apaceram™ is intended to be placed into bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine, or pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. It also can be used with autograft as a bone graft extender. Apaceram™ is resorbed and replaced with bone during the healing process.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120602