510(k) Summary for the Cerasorb® MIX

AUG 19 2010

1. SUBMITTER/510(K) HOLDER

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Date Prepared: August 16, 2010

2. DEVICE NAME

Trade Name:	Cerasorb® MIX
Common Name:	Bone Void Filler
Classification Name:	Filler, bone void, calcium compound, 21CFR 888.3045, Product Code MQV

3. PREDICATE DEVICES

- Cerasorb® Ortho granules subject of K014156
- Cerasorb® M Ortho granules subject of K040216

4. DEVICE DESCRIPTION

The Cerasorb® MIX Device is a mixture of two legally marketed bone void filler devices, the Cerasorb Ortho granules subject of K014156 and Cerasorb M Ortho granules subject of K040216. The bone replacement and bone regeneration material Cerasorb MIX consists of ≥99% pure phase beta-tricalcium phosphate (beta-TCP). The Cerasorb® and Cerasorb® M mixture includes granule sizes of 500-1000 µm and 1000-2000 µm. The mixing ratio is 1cc to 1cc of Cerasorb® and Cerasorb® M granules.

The material should not be packed in dry form; it should be mixed with autologous blood (blood from the void or venous blood). The implanted material must be in direct contact with the bleeding vital bone.

K100841

5. INTENDED USE

Cerasorb® MIX is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structures. It is indicated for filling of bone defects, caused by surgery, trauma or degenerative process. Cerasorb® MIX granules are intended to be gently packed into the bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, and pelvis). Cerasorb® MIX is not indicated for use in load-bearing applications. It does not possess sufficient mechanical strength, therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization. Following placement in the bony voids or gaps, the Beta-tricalcium phosphate granules are gradually resorbed and replaced with new bone.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Since the Cerasorb® MIX device is a mixture of two legally marketed bone void filler devices, the Cerasorb Ortho granules subject of K014156 and Cerasorb M Ortho granules subject of K040216, the technological characteristics are identical to that described in the previously cleared 510(k) premarket notifications. The bone replacement and bone regeneration material Cerasorb® MIX consists of ≥99% pure phase beta-tricalcium phosphate (beta-TCP). The Cerasorb® and Cerasorb® M mixture includes granule sizes of 500-1000µm and 1000-2000 µm. The mixing ratio is 1cc to 1cc. Cerasorb® and Cerasorb® M granules.

Side-by-Side Comparison of Bone Optimizer with Predicate Devices

	Cerasorb® MIX Device	**Predicate Cerasorb Ortho Granules**	**Predicate Cerasorb M Ortho Granules**
Regulatory Status	Proposed	K014156	K040216
Target population	For patients with bony voids or gaps resulting from surgery, trauma or degenerative processes and which are not intrinsic to the stability of the bony structure.		
Labeling	Labeling contains same intended use, contraindications, warnings, precautions, and adverse events as predicate.	same	Labeling contains same intended use, contraindications, warnings, precautions, and adverse events as predicate.
Performance	Osteoconductive	Osteoconductive	Osteoconductive
Sizes	500 – 2000µm	50 – 2000µm	50 µm -8000µm
Porosity	>0 to 500 µm	Micropores >0<80 µm	Interconnecting micro, meso-, and macropores (0 - 500 µm)
Sterility	Sterile, Non-pyrogenic Single patient use	Sterile, Non-pyrogenic Single patient use	Sterile, Non-pyrogenic Single patient use
Bio-compatibility	Established	Established	Established
Mechanical safety	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site

K100841

7. PERFORMANCE TESTING

The only difference between the proposed device and the predicate devices is that the Cerasorb® MIX device is constructed of two forms of previously cleared calcium phosphate salts. This does not affect safety or effectiveness since they are all resorbable and carry out the same function. The safety and biocompatibility testing performed for calcium phosphates (found in K014156 and K040216) and the long history of safe clinical use. Curasan believes that the proposed device has the identical technological characteristics as the predicate devices; therefore, the Cerasorb® MIX device should behave and function exactly as the parent devices and therefore no new testing is required. Testing performed on the proposed device contained in K014156 and K040216 confirmed that the Cerasorb® MIX device meets the applicable requirements of the FDA guidance documents on bone void fillers. Therefore, the differences in material forms between the proposed and predicate devices do not impact the safety or effectiveness of the device.

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

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% Medical Device Consultants, Inc.
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AUG 19 2010

Re: K100841
Trade/Device Name: Cerasorb® MIX
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: July 19, 2010
Received: July 21, 2010

Dear Dr. Nolte:

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K100841

Indications for Use

510(k) Number (if known): K100841

Device Name: Cerasorb® MIX

Indications for Use:

Cerasorb® MIX is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structures. It is indicated for filling of bone defects, caused by surgery, trauma or degenerative process. Cerasorb® MIX granules are intended to be gently packed into the bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine, and pelvis). Cerasorb® MIX is not indicated for use in load-bearing applications. It does not possess sufficient mechanical strength, therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization. Following placement in the bony voids or gaps, the Beta-tricalcium phosphate granules are gradually resorbed and replaced with new bone.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100841