K040216

MAR 2 6 2004

curasan

Special 510 (K) Summary: Line Extension to Cerasorb® ORTHO (granular form)

Submission Information:

Name and Address of the Sponsor:	curasan AG Lindigstrasse 4 63801 Kleinostheim Germany
Contact person:	Stefan Meiners Head of Regulatory Affairs and Quality Management Tel.: ++49 – 6027 – 4686-94 Fax: ++49 – 6027 – 4686-33 E – Mail: stefan.meiners@curasan.de
Registered U. S. agent:	Dr. Eric Wiechert 109 Shore Drive Garner, NC 27529 USA Phone: 919 – 772-8518, fax: 919 – 772-1300 E – Mail: ewiecher@bellsouth.net

Device Identification:

Proprietary Name:	Cerasorb® M ORTHO
Common Name:	Bone Void Filler
Classification:	Class II

Predicate Devices:

Cerasorb® ORTHO (granular form):	Bone void filler consisting of pure phase Beta-Tricalcium Phosphate.
Cerasorb® ORTHO (block forms):	Bone void filler, block forms consisting of pure phase Beta-Tricalcium Phosphate
Vitoss Scaffold Synthetic:	Bone void filler, granules, block forms and morsels consisting of Beta-Tricalcium Phosphate

Description of the Device Modification:

The device modification is a change in the shape resp. size of the bone void filler. The predicate device Cerasorb® ORTHO, a synthetic, porous, resorbable and osteoconductive bone void filler, was developed in granular form (spherical granules) of different diameter (500-1000µm, 1000-2000µm) to be filled in the bone void(s). The material consists of pure phase Beta-Tricalcium Phosphate of interconnecting porosity.

This submission is intended to address a modification in the shape of the bone void filler. The bone void filler is now additionally presented as polygonal shaped morsels of different sizes ranging from 50µm to 8000µm. The pure phase Beta-Tricalcium Phosphate material is of interconnecting microporosity and additionally contains defined interconnecting meso-, and macropores (50 – 500 µm).

Intended Use:

Cerasorb® M ORTHO (morsels) is intended for use as a bone void filler in voids or gaps (resulting from surgery, trauma or degenerative processes) in the skeletal system (extremities, spine, pelvis) that are not intrinsic to the stability of the bony structure. Following placement in the bony void or gap, the ß-TCP ceramic material is gradually resorbed and replaced with bone. The placement of Cerasorb® M ORTHO should not be in dry form, the material should be mixed with autologous blood.

Statement of technological comparison

All design modifications consist of pure phase Beta-Tricalcium Phosphate ceramic material according to ASTM F 1088-87, reapp. 1992. The material is of interconnecting porosity, osteoconductive and resorbable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2004

Curasan AG
C/o Eric Wiechert, Ph.D., RAC
President
Applications Specialists International, Inc.
109 Shore Drive
Garner, North Carolina 27529

Re: K040216
Trade/Device Name: Cerasorb® M ORTHO
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: March 12, 2004
Received: March 18, 2004

Dear Dr. Wiechert:

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.

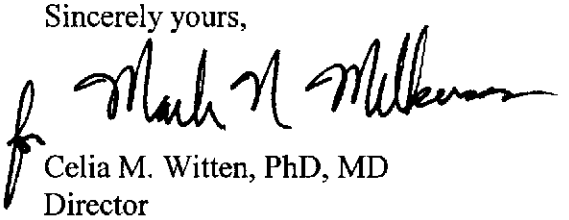
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, PhD, MD
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): K040216

Device Name: Cerasorb® M ORTHO

Indications for Use:

Cerasorb® M ORTHO (polygonal broken morsels) is intended for use as a bone void filler in voids or gaps (resulting from surgery, trauma or degenerative processes) in the skeletal system (e.g. extremities, spine, pelvis) that are not intrinsic to the stability of the bony structure. Following placement in the bony void or gap, the ß-TCP ceramic material is gradually resorbed and replaced with bone. The placement of Cerasorb® M ORTHO should not be in dry form, the material should be mixed with autologous blood.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

for Mark N Milhern

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

510(k) Number K040216