K050260

Section 2: 510(K) Summary of Safety and Effectiveness
BioResorb® Macro Pore

JUL 15 2005

A. Submitters Information

Name:	Oraltronics Dental Implant Technology GmbH.
Address:	Herrlichkeit 4 Bremen, DE 28199
Telephone:	49-421-4-39390
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Contact Person:	Dr. Greggory Cox
Date of Submission:	January 28, 2005

B. Device Name

BioResorb® Macro Pore

C. Predicate Device

Curasan Cersorb® Ortho, K014156, Curasan AG, Lindstrasse 4, Kleinostheim, Germany

D. Device Description

BioResorb® Macro Pore ß tricalcium phosphate is a synthetic, resorbable bone void filling material.

E. Intended Use

BioResorb® Macro Pore is to be used as a bone void filler device used in guided tissue regeneration, sinus lifts, ridge maintenance, alveolar socket preservation or ridge augmentation and the treatment of osseous defects.

F. Technological Characteristics

The proposed BioResorb® Macro Pore and the predicate device Cerasorb® are of identical composition and are intended for the same use. The technological characteristics of the materials used are exact to the predicate device.

G. Performance Data

BioResorb® is a ceramics powder of phase-three ß-TCP. It is manufactured from pure laboratory chemicals. The contents of heavy metal according to ASTM 1088 (Standard specification for beta-TCP for implant surgery) are far below the permissible levels. BioResorb® has been used and marketed in Germany since 1988 with no adverse events. The safety and effectiveness of this material ß-TCP in this application has been established.

The proposed BioResorb® Macro Pore device is substantially equivalent to the listed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2007

Oraltronics Dental Implant Technology GmbH
C/O Mr. Chad Bartee
Osteogenics Biomedical, Incorporated
3234 64th Street
Lubbock, Texas 79413

Re: K050260
Trade/Device Name: BioResorb® Macro Pore
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: July 6, 2005
Received: July 7, 2005

Dear Mr. Bartee:

This letter corrects our substantially equivalent letter of July 15, 2005.

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 (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); 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 continue 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) 276-0115 (http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): 050260

Device Name: BioResorb® Macro Pore

Indications for Use:

BioResorb® is to be used as a bone void filler device used in guided tissue regeneration, sinus lifts, ridge maintenance, alveolar socket preservation or ridge augmentation, and the treatment of osseous defects.

Prescription Use __X__ (Per 21 CFR 801.109) OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Betz DDS for Dr. Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050260