

**510(k) Summary**

**Mathys Ltd  
Ceros<sup>®</sup> TCP Granules**

September 9, 2010

ADMINISTRATIVE INFORMATION

SEP 15 2010

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Ceros<sup>®</sup> TCP Granules  
Common Name: Bone Grafting Material, Synthetic  
Classification Regulations: 21 CFR 872.3930  
Product Code: LYC  
Classification Panel: Dental Products Panel  
Reviewing Branch: Dental Devices Branch

INTENDED USE

Ceros<sup>®</sup> TCP Granules are indicated for use as a bone void filler in non-loadbearing areas in the oral and maxillofacial regions requiring cancellous rather than cortical bone material. Ceros<sup>®</sup> TCP Granules may, for example, be used for:

- supplementing autogenous cancellous bone
- supporting and stabilizing for guided bone regeneration, “GBR”
- filling bone cavities after hemisection of teeth, bone removal, osteotomy, tumor resection, root apex resection, tooth extraction or cystectomy
- filling bone defects resulting from traumatic or pathological origin
- augmenting an atrophied mandibular ridge (only in conjunction with the “GBR” membrane technique)
- filling defects after explantation of dental implants
- filling small periodontal bone cavities as well as bi- and tri-furcations of teeth
- the reconstruction of alveolar defects prior to providing a prosthesis
- preparation of the implant bed (e.g. sinus lift)
- filling bone defects around dental implant after immediate placement into extraction sockets

Ceros<sup>®</sup> TCP Granules are intended to be gently packed or placed into the surgical site and may be combined with autogenous blood, bone marrow or saline.

#### DEVICE DESCRIPTION

Ceros<sup>®</sup> TCP Granules are a synthetic, porous, osteoconductive, bioresorbable bone grafting material composed of beta-tricalcium phosphate,  $\beta$ -TCP, [ $\beta$ -Ca<sub>3</sub>(PO<sub>4</sub>)<sub>2</sub>] intended to fill, augment, or reconstruct bony defects in dental, oral or maxillofacial surgery. Ceros<sup>®</sup> TCP Granules are provided in volumes of 0.5, 1.0 and 2.5 g.

#### EQUIVALENCE TO MARKETED DEVICE

Mathys Ltd demonstrated that for the purposes of FDA’s regulation of medical devices, Ceros<sup>®</sup> TCP Granules are substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

- Synthes (USA) chronOS<sup>™</sup> -  $\beta$ -TCP cleared under K053022,
- Curasan AG Cerasorb<sup>®</sup> DENTAL and Cerasorb<sup>®</sup> M DENTAL cleared under K051443
- BioForm, Inc., Calcium Hydroxylapatite Implant cleared under K030682.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject device is made of  $\beta$ -TCP, [ $\beta$ -Ca<sub>3</sub>(PO<sub>4</sub>)<sub>2</sub>] conforming to ASTM F1088 *Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation*. Predicate devices are made of  $\beta$ -TCP or a similar material, CaHA, with similar particle size, pore size and porosity to the subject device. Subject and predicate devices are packaged in similar materials and sterilized using similar methods.

Bench testing was performed to demonstrate conformance to ASTM F1088, including chemical composition by inductively coupled plasma and x-ray fluorescence,  $\beta$ -TCP content by quantitative x-ray diffraction, and trace element analysis by inductively coupled plasma/mass spectroscopy. Testing was also performed to characterize physical characteristics including particle size and particle size distribution by optical image analysis and surface morphology by scanning electron microscopy. Dissolution testing was performed according to ISO 10993-14.

In summary, Ceros® TCP Granules have the following similarities to the predicate devices:

- have the same intended use,
- use the same operating principle,
- incorporate the same basic design,
- incorporate the same or very similar materials, and
- have similar packaging and is sterilized using the same materials and processes.



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

Mathys Limited  
C/O Ms. Linda Schulz  
PaxMed International LLC  
11234 El Camino Real, Suite 200  
San Diego, California 92130-8587

SEP 15 2010

Re: K101426  
Trade/Device Name: Ceros<sup>®</sup> TCP Granules  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: II  
Product Code: LYC  
Dated: August 16, 2010  
Received: August 17, 2010

Dear Ms. Schulz:

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" (21 CFR 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,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number: K101426

Device Name: Ceros<sup>®</sup> TCP Granules

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Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (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)

Susan Currier Page 1 of \_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K101426