K103769

curasan

Appendix B

MAR 10 2011

510(k) Summary in accordance with 21 CFR 807.92(c)

Device Name:	Ceracell® DENTAL
Type of 510(k) submission:	Abbreviated
Date of Submission:	17 December 2010
Manufacturer:	Curasan AG, Frankfurt Facility In Der Schildwacht 13 65933Frankfurt Germany
FDA Registration Number:	3004847139
510(k) Owner:	Curasan AG Lindigstrasse 4 63801 Kleinostheim Germany Phone: +49 (0)60 27 40 900 0 Fax: +49 (0)60 27 40 900 29
FDA Registration Number:	3003771570
510(k) Submitter and Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy Phone: +39 06 578 2665 Fax: +30 06 574 3786 Email: rgray@donawa.com
FDA Product Code:	LPK
FDA Regulation Number:	872.3930
FDA Classification Name:	Dental Bone Grafting Material
Common Name:	Tricalcium phosphate bone grafting material
FDA Panel:	Dental
FDA Classification:	Class II
FDA Identification:	Bone grafting material is a material such as hydroxyapatite, tricalcium phosphate, polylactic and polyglycolic acids, or collagen, that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.
FDA Guidance Applied:	Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices

Indications for Use:

Ceracell® DENTAL is indicated for:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filing of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of perio-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Technological and Performance Characteristics:

Ceracell® DENTAL is a synthetic absorbable radiopaque bio-ceramic for dental and maxillofacial bone regeneration, using pure phase beta-tricalcium phosphate with an open-cell sintered structure of biocompatible, bioactive organic and osteoconductive material.

Ceracell® DENTAL polygonal 'morsels' have a porosity of approximately 80% and are available in a grain sizes from 150 – 2,000 µm, with the intended use of filling dental and maxillofacial bone defects. This level of porosity allows rapid ingrowth of the bone, and blood components are able to permeate the material, leading to osseous integration and vascularisation.

The material is doped with 4% sodium-magnesium-silicate to provide mechanical stability.

Ceracell® DENTAL morsels are available in a range of morsel sizes and quantities.

The final product is packed in glass vials, fitted with brombutyl rubber stoppers, then subjected to a gamma radiation sterilization process before being packed in outer cartons.

Resorption time varies with technique from 4 to 12 months.

Comparison with predicate device:

The predicate device selected for comparison with Ceracell® DENTAL is identified as follows:

Device:..... Cerasorb® Dental
510(k) Sponsor:..... Curasan AG
510(k) Number:..... K051443
Clearance Date:..... 3 August 2005
FDA Product Code:..... LPK
Classification Name:..... Tricalcium phosphate granule for dental bone repair
Regulation No:..... 872.3930

The majority of the device characteristics for Ceracell® DENTAL are identical to those of the predicate device. Where they are not identical (device composition, volumetric porosity and phase purity), they are very similar, and these differences have no significant effect on device safety or effectiveness.

Conclusion:

Based on the information contained within this submission, it is concluded that Ceracell® DENTAL is substantially equivalent to the predicate device already in interstate commerce within the USA.

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

Curasan AG
C/O Mr. Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania, 10
00153 Rome
ITALY

MAR 10 2011

Re: K103709
Trade/Device Name: Curasan Ceracell® DENTAL
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Codes: LPK and LYC
Dated: December 17, 2010
Received: December 20, 2010

Dear Mr. Gray:

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,

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

Appendix A

Indications for Use Statement

510(k) Number (if known): Not known (K103709)

Device Name: Curasan Ceracell® DENTAL

Indications for Use: Ceracell® DENTAL is indicated for:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filing of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of perio-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Prescription Use (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K103709