K111105

curasan

Appendix B

DEC 2 0 2012

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

Device Name:	Osseolive® DENTAL
Type of 510(k) submission:	Abbreviated
Date of Submission:	15 April 2011
Manufacturer:	Curasan AG, Frankfurt Facility Ernst-Wiss-Strasse 18 65933 Frankfurt 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:	LYC
FDA Regulation Number:	872.3930
FDA Classification Name:	Dental Bone Grafting Material
Common Name:	Glass ceramic 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:

Osseolive® DENTAL is indicated for applications in oral and maxillofacial surgery and dentistry, including filling and/or reconstruction of multi-walled (artificial or degenerative) bone defects, e.g.:

- Defects after the extirpation of bone cysts
- Augmentation of an atrophied alveolar ridge
- Sinus lift or sinus floor elevation (subantral augmentation)
- Filing of alveolar defects after tooth extraction for preservation of the alveolar ridge
- Filling of extraction defects to create an implant bed
- Filling of two- or multi-walled bone pockets as well as the bi- and trifurcation defects
- Defects after operative removal of retained teeth or corrective osteotomies

Technological and Performance Characteristics:

Osseolive® DENTAL is a synthetic absorbable radiopaque silicated calcium-alkali-phosphate ceramic for filling, bridging and reconstructing bone defects and for bone fusion in dental and maxillofacial applications.

Description

Osseolive® DENTAL has an open-cellular porosity of about 80% and is available as polygonal granules of various grain sizes. It is resorbed by the body over a period of months and simultaneously substituted by local autologous bone. As a synthetic, bioactive ceramic material Osseolive® DENTAL has excellent intra- and extra-osseous tissue compatibility and is neither locally nor systemically toxic.

Osseolive® DENTAL is a calcium-potassium-sodium phosphate with an open sintered structure. Osseolive® DENTAL morsels are highly porous, available in different grain size fractions between 150 and 2000 µm. The high porosity allows blood components and body fluids to penetrate the material rapidly and unhindered.

The chemical composition is a modification of tricalcium phosphate, where one calcium atom is replaced by one potassium atom and one sodium atom, resulting in increased solubility.

Doping this glass ceramic with 4% sodium-magnesium-silicate on interstitial positions ensures the maximum mechanical stability.

Osseolive® DENTAL has a resorption time of 3 to 12 months.

Osseolive® DENTAL morsels are packaged for sale in glass vials.

Predicate Device Comparison:

The predicate devices selected for comparison with Osseolive® DENTAL are identified as follows:

Device: ..... PerioGlas
510(k) Sponsor: ..... NovaBone Products, LLC
510(k) Number: K053387
Clearance Date: ..... 14 February 2006
FDA Product Code: ..... LYC
Classification Name: ..... Bone grafting material, synthetic
Regulation No: 872.3930

Device: ..... Ceracell® DENTAL
510(k) Sponsor: ..... Curasan AG
510(k) Number: K103709
Clearance Date: ..... 10 March 2011
FDA Product Code: ..... LYC
Classification Name: ..... Bone grafting material, synthetic

Regulation No: 872.3930

Device: ..... Cerasorb® M DENTAL
510(k) Sponsor: ..... Curasan AG
510(k) Number: K051443
Clearance Date: ..... 22 July 2005
FDA Product Code: ..... LYC
Classification Name: ..... Bone grafting material, synthetic
Regulation No: 872.3930

Bench test summary:

Comparative testing of the subject device and predicate devices was undertaken by a GLP compliant third party test laboratory. The following material characteristics were assessed for each device for comparison purposes:

- Analyses of inorganic elements
- Determination of bulk density according to USP 34 <616> and porosity
- X-ray characterization
- FTIR characterization
- Characterization of crystallinity
- Phase analyses
- Determination of the specific surfaces (B.E.T. method) according to ASTM C 1251 and ASTM D 4780
- Micro structure characterization according to ISO 6474 and ASTM E 112
- Determination of Ca/P ratio per mass test material
- Identification and qualification of degradation products according to DIN EN ISO 10993-14
- Determination of the pH value according to USP 34 <791>

Comparison summary:

The majority of the device characteristics for Osseolive® DENTAL are similar to one or more of the predicate devices. Where they are not similar, the differences have no significant effect on device safety or effectiveness.

Conclusion:

Based on the information contained within this submission, it is concluded that the Osseolive® DENTAL is substantially equivalent to the identified predicate devices 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 Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2012

Curasan AG
C/O Mr. Roger Gray
Vice President Quality and Regulatory
Donawa Lifescience Consulting SRL
Piazze Albania 10
Rome, Italy 00153

Re: K111105
Trade/Device Name: Curasan Osseolive® DENTAL
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: December 14, 2012
Received: December 17, 2012

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,
Respiratory, 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): K111105

Device Name: Curasan Osseolive® DENTAL

Indications for Use: Osseolive® DENTAL is indicated for applications in oral and maxillofacial surgery and dentistry, including filling and/or reconstruction of multi-walled (artificial or degenerative) bone defects, e.g.:

- Defects after the extirpation of bone cysts
- Augmentation of an atrophied alveolar ridge
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- Filling of two- or multi-walled bone pockets as well as the bi- and trifurcation defects
- Defects after operative removal of retained teeth or corrective osteotomies

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 DDS, MA 2012.12.20 06:52:57 -05'00'

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

510(k) Number: K111105