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 2, 2016

Curasan AG
% Dr. Karin Lübbers
Managing Director
YES Medical Device Services GmbH
Bahnstrasse 42-46
Friedrichsdorf, Hesse 61381
Germany

Re: K160566
Trade/Device Name: Cerasorb Ortho Foam
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: October 28, 2016
Received: October 31, 2016

Dear Dr. Lübbers:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160566

Device Name
Cerasorb Ortho Foam

Indications for Use *(Describe)*
Cerasorb Ortho Foam is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Cerasorb Ortho Foam resorbs and is replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Submitter

This 510(k) application was created in January 2016

The 510(k) owner for this application is:

Company	curasan AG
Address	Lindigstr. 4 63801 Kleinostheim Germany
Phone:	+49-6027-40900-0
Fax:	+49-6027-40900-29
Email:	info@curasan.de
Establishment registration number:	3003771570

Contact person:

Name:	Dr. Wolf-Dietrich Hübner
Position:	Medical Director

2. Device Name and Classification

Proprietary / Trade Name:	Cerasorb Ortho Foam
Common Name:	Bone Void Filler
Classification Name:	Filler, Bone Void, Calcium Compound
Classification:	Class II per 21 CFR § 888.3045
Product Code	MQV
Panel	Orthopedic

3. Predicate Device

This application claims that Cerasorb Ortho Foam is substantially equivalent to the following predicate device:

510(k) number	K 032288
Proprietary / Trade Name:	Vitoss Scaffold Foam Bone Graft Material
Common Name:	Bone Void Filler
Classification Name:	Filler, Bone Void, Calcium Compound
Classification:	Class II per 21 CFR § 888.3045
Product Code	MQV
Panel	Orthopedic
Manufacturer	Orthovita, Inc., 45 Great Valley Parkway, Malvern, PA 19355

4. Description

Cerasorb Ortho Foam is a highly porous composite material for bone augmentation and regeneration applications, consisting of porcine collagen and a resorbable ceramic. Through the use of pure phase β-tricalcium phosphate with a regular interconnected porous structure, a degradation of the biomaterial is achieved simultaneously to natural bone regeneration. The pure phase β-tricalcium phosphate is made according to ASTM F 1088-04a. The β-tricalcium phosphate component of Cerasorb Ortho Foam is a mixture of Cerasorb M Ortho and Cerasorb Ortho, which received previous 510(k) clearances (K040216 and K014156, respectively). The device has been tested to meet pyrogen limit specifications.

Cerasorb Ortho Foam is available in five different sizes and two versions (mouldable foam and flexible foam strip) and serves to fill bone defects in the entire skeletal system.

Available sizes:

Product name	Dimensions LxWxH [mm]
Cerasorb Ortho Mouldable Foam	25x25x4
Cerasorb Ortho Mouldable Foam	25x50x4
Cerasorb Ortho Mouldable Foam	25x100x4
Cerasorb Ortho Flexible Foam Strip	25x50x4
Cerasorb Ortho Flexible Foam Strip	25x100x4

5. Intended Use

Cerasorb Ortho Foam is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Cerasorb Ortho Foam resorbs and is replaced with bone during the healing process.

6. Substantial Equivalence

Cerasorb Ortho Foam is substantially equivalent to the predicate device Vitoss Scaffold Foam Bone Graft Material. Please refer to the table below that discusses the substantial equivalence of the two devices in detail.

Device Comparison Table		
Feature	**Proposed device: Cerasorb Ortho Foam**	**Predicate device Vitoss Scaffold Foam Bone Graft Material**
Intended use	Cerasorb Ortho Foam is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Cerasorb Ortho Foam resorbs and is replaced with bone during the healing process.	Vitoss Scaffold Foam Bone Graft Material is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Scaffold Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Vitoss Scaffold Foam should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. Vitoss Scaffold Foam Bone Graft Material is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.
Abbreviated intended use	Bone void filler	Bone void filler

Device Comparison Table		
Feature	**Proposed device: Cerasorb Ortho Foam**	**Predicate device Vitoss Scaffold Foam Bone Graft Material**
Target Population	Individual with bony defect resulting from surgery or trauma	Individual with bony defect resulting from surgery or trauma
Anatomical locations	Bony voids or gaps of the skeletal system, i. e., the extremities and pelvis	Bony voids or gaps of the skeletal system, i. e., the extremities, spine and pelvis
Labeling	Contains comparable intended use, warnings, and precautions as the labeling of the Vitoss Scaffold Foam Bone Graft Material. The wording is not identical, but substantially equivalent.	-
Materials		
Chemical composition	Calcium salt with Type I and Type III porcine collagen	Calcium salt with Type I bovine collagen
Mineral phases	β-Tricalcium phosphate $Ca_3(PO_4)_2$	β-Tricalcium phosphate $Ca_3(PO_4)_2$
Design		
Physical structure	Trabecular structure similar to cancellos bone	Trabecular structure similar to cancellos bone
Pore size (range)	0.1-500 µm	1-1000 µm
Performance		
Osteoconductivity	Osteoconductive	Osteoconductive
Mechanical strength	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site
Sterility	Sterilized by gamma irradiation, single use only	Sterilized by gamma irradiation, single use only
Biocompatibility	Established	Established
Dosage Form(s)	Strips, Packs	Cylinders (Blocks), Strips, Packs, Flow, Shapes

One difference between Cerasorb Ortho Foam and the predicate device is that porcine collagen type I and type III was used instead of bovine collagen. This change was done for safety reasons as for porcine collagen the risk of Transmissible Spongiform Encephalopathy transmission is reduced. Moreover, the pore size of the integrated β-tricalcium phosphate particles is on the average smaller for Cerasorb Ortho Foam, but within the same range. No significant functional implications are expected.

Based on the identified characteristics it is claimed that the device is substantially equivalent to the predicate device.

7. Performance Testing

A comparative study in sheep using the critical size defect model was performed. Cerasorb Ortho Flexible Foam Strip and Cerasorb Ortho Mouldable Foam were tested and compared to the predicate device Vitoss Scaffold Foam Bone Graft Material. The amount and quality

of the newly formed bone was evaluated as well as the occurrence of fibrosis and inflammation at the surgical site. It was concluded that Cerasorb Ortho Flexible Foam Strip and Cerasorb Ortho Mouldable Foam performed at least as well as the predicate device Vitoss Scaffold Foam Bone Graft.

Based on the functional testing performed, substantial equivalence to the predicate device Vitoss Scaffold Foam Bone Graft Material is given.