September 17, 2018

curasan AG
% Kevin A. Thomas, Ph.D.
Vice President, Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K181721
Trade/Device Name: Ceracell® 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: June 28, 2018
Received: June 29, 2018

Dear Dr. Thomas:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For 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)*

K181721

Device Name

Ceracell® Ortho Foam

Indications for Use *(Describe)*

Ceracell® Ortho Foam is intended to fill bony voids or gaps of the skeletal system (posterolateral spine). These osseous defects may be surgically created or from traumatic injury to the bone and are not intrinsic to the stability of the bony structure. In the posterolateral spine Ceracell® Ortho Foam is to be mixed with autograft bone. The device 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
Ceracell® Ortho Foam
curasan AG

June 28, 2018

ADMINISTRATIVE INFORMATION

Manufacturer Name	curasan AG Lindigstrasse 4 Kleinostheim, 63801 Germany Telephone +49 6027-40900-0 Fax +49 6027-40900-19
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Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Ceracell® Ortho Foam
Common Name	Filler, bone void, calcium compound
Classification Name	Resorbable calcium salt bone void filler device
Classification Regulations	21 CFR 888.3045, Class II
Product Code	MQV
Classification Panel	Orthopaedic and Rehabilitation Devices Panel
Reviewing Branch	Restorative and Repair Devices Branch (RRDB)

PREDICATE DEVICE INFORMATION

The primary predicate device is K140375, MASTERGRAFT® Strip; MASTERGRAFT® Putty, Medtronic Sofamor Danek USA, Inc. The reference predicate devices are K160566, Cerasorb Ortho Foam, curasan AG, and K103709, Curasan Ceracell® DENTAL, curasan AG.

INDICATIONS FOR USE

Ceracell® Ortho Foam is intended to fill bony voids or gaps of the skeletal system (posterolateral spine). These osseous defects may be surgically created or from traumatic injury to the bone and are not intrinsic to the stability of the bony structure. In the posterolateral spine Ceracell® Ortho Foam is to be mixed with autograft bone. The device resorbs and is replaced with bone during the healing process.

SUBJECT DEVICE DESCRIPTION

Ceracell® Ortho Foam is a porous composite material consisting of resorbable β-tricalcium phosphate ceramic granules (85% by weight of the final device) in a porcine collagen scaffold (Type I and Type III, 15% by weight of the final device). The porcine collagen scaffold component of the subject device is identical to the collagen component of curasan AG's previously cleared device, Cerasorb Ortho Foam, K160566. The ceramic component of the subject device (β-tricalcium phosphate with approximately 4% SiO_2-MgO-Na_2O) is identical to the ceramic component of curasan AG's previously cleared device, Curasan Ceracell® DENTAL, K103709.

Ceracell® Ortho Foam is provided as Ceracell® Ortho Flexible Foam Strip and Ceracell® Ortho Moldable Foam. Ceracell® Ortho Flexible Foam Strip is provided in various sizes from 2.5 cc to 25 cc. Ceracell® Ortho Moldable Foam is provided in various sizes from 1.2 cc to 25 cc.

PERFORMANCE DATA

Pre-clinical testing data were submitted according to the guidance documents *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device* (issued June 2003) and *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (issued January 2016). The pre-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included chemical composition, physical properties, biocompatibility, sterilization, material mediated pyrogenicity, bacterial endotoxin, sterile barrier shelf life, and product shelf life.

Animal testing performed to demonstrate substantial equivalence included determination of radiographic, histologic, and histomorphometric characteristics of the subject device and the predicate device in a rabbit posterolateral spine fusion model. Animals implanted with autograft (positive control) also were evaluated. The study time points included baseline (time 0), 6 weeks, 9 weeks, and 12 weeks. Evaluation endpoints included manual palpation, range of motion/flexibility testing, plain and high-resolution radiography, micro-computed tomography (micro-CT) imaging, undecalcified histologic evaluation, and histomorphometric analysis. Decalcified paraffin histology sections also were graded according to AAMI/ANSI/ISO 10993-6 (Annex E).

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

curasan AG submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the legally marketed predicate devices:

K140375, MASTERGRAFT® Strip; MASTERGRAFT® Putty, Medtronic Sofamor Danek USA, Inc.;

K160566, Cerasorb Ortho Foam, curasan AG; and

K103709, Curasan Ceracell® DENTAL, curasan AG.

A comparison of the technological characteristics of the subject device and the primary predicate device K140375 is provided in the following table.

Comparison	Subject Device	Primary Predicate Device
	Ceracell® Ortho Foam curasan AG	K140375 MASTERGRAFT® Strip; MASTERGRAFT® Putty Medtronic Sofamor Danek USA, Inc.
Indications for Use Statement	Ceracell® Ortho Foam is intended to fill bony voids or gaps of the skeletal system (posterolateral spine). These osseous defects may be surgically created or from traumatic injury to the bone and are not intrinsic to the stability of the bony structure. In the posterolateral spine Ceracell® Ortho Foam is to be mixed with autograft bone. The device resorbs and is replaced with bone during the healing process.	MASTERGRAFT® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure: Additionally. MASTERGRAFT® Putty can be used with autograft as a bone graft extender. MASTERGRAFT® Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis. ilium. and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® Putty resorbs and is replaced with bone during the healing process.
Product Code	MQV	MQV
Intended Use	Bone void filler for skeletal system (posterolateral spine)	Bone void filler for skeletal system (extremities, pelvis, and posterolateral spine)
Use in Spine	Yes	Yes
Hydration prior to use	Sterile saline (required)	Bone marrow aspirate and/or sterile water (required)
Mix with bone prior to use	Autograft bone (required)	Autograft bone (optional)
Design		
Form	Granules uniformly dispersed in collagen scaffold 85 wt % granules, 15 wt % collagen	Granules uniformly dispersed in collagen scaffold
Granule Size	1000-2000 µm	0.5 mm – 1.6 mm in diameter
Porosity	Granules – up to 75% Final device (granules in collagen scaffold) – 80%	Granules – 80% Final device – not stated in 510(k) Summary
Materials		
Calcium salts	β-tricalcium phosphate with approximately 4% SiO_2-MgO-Na_2O	β-tricalcium phosphate (85%) and Hydroxyapatite (15%)
Scaffold/Binder	Type I and Type III porcine collagen (15 wt % of total material)	Type I bovine collagen
How Provided		
Sizes, shapes	Flexible Foam Strip 25 x 25 x 4 mm (2.5 cc) 25 x 50 x 4 mm (5 cc) 25 x 100 x 4 mm (10 cc) 65 x 65 x 6 mm (25 cc) Moldable Foam 25 x 12 x 4 mm (1.2 cc) 25 x 25 x 4 mm (2.5 cc) 25 x 50 x 4 mm (5 cc) 25 x 100 x 4 mm (10 cc) 65 x 65 x 6 mm (25 cc)	MASTERGRAFT® Putty Various volumes: 0.75 cc, 1.5 cc, 3.0 cc, 6.0 cc, and 9.0 cc packages
Single use	Provided sterile to end-user	Provided sterile to end-user
Sterile	Gamma irradiation	Not stated
Sterilization	Single-patient, single-use	Single-patient, single-use

The primary predicate device is K140375 for substantial equivalence in the animal model performance testing. The reference predicate devices K160566 and K103709 are for support of substantial equivalence in terms of the subject device material composition.

The subject device and the primary predicate device K140375 have the same intended use, the same product classification and product code (MQV), and have similar Indications for Use statements. The

subject device and the primary predicate devices are bone void fillers that are intended for bony voids or gaps that are not intrinsic to the stability of the bony structure. The subject device and primary predicate device are indicated for use in the posterolateral spine with autograft bone (extender). Although the subject device and the primary predicate have slightly different Indications for Use language, this difference in language does not change the intended use as a bone void filler in the posterolateral spine.

The subject device and the primary predicate device K140375 each incorporate calcium phosphate materials within a collagen scaffold. The subject device scaffold is Type I and Type III porcine collagen, and the primary predicate K140375 scaffold is Type I bovine collagen. The subject device is made of the identical collagen as the reference predicate device K160566, and the subject device is made of identical calcium phosphate component as the reference predicate device K103709. The subject device and all predicate devices are provided sterile for single-patient, single-use in similar ranges of graft volumes.

The radiographic, histologic, and histomorphometric performance of the subject device were compared to that of the primary predicate device K140375 in a rabbit posterolateral fusion model. The results of the study demonstrated that the performance of the subject device was equivalent to that of the primary predicate device K140375.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.