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

January 13, 2017

Skeletal Kinetics, LLC.
Alicia Hemphill
Director, Regulatory Affairs
10201 Bubb Road
Cupertino, California 95014

Re: K162864
Trade/Device Name: OsteoVation Impact
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate For Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: October 12, 2016
Received: October 13, 2016

Dear Ms. Hemphill:

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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K162864

Device Name
OsteoVation® Impact

Indications for Use *(Describe)*
OsteoVation Impact is a calcium phosphate bone void filler indicated for the repair or filling of neurosurgical burr holes, other cranialbone defects and craniotomy cuts with a surface area no larger than 25cm2. OsteoVation Impact may be used in the restoration or augmentation of bony contours of the cranialbone skeleton.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael J. Hoffmann -S

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

I. SUBMITTER

Skeletal Kinetics
10201 Bubb Road
Cupertino, CA 95014 USA

Phone: 972-677-4783
Fax: 972-677-4601
Email: ahemphill@osteomed.com

Contact Person: Alicia Hemphill
Date Prepared: January 12, 2017

Establishment Registration: 3003890476

II. DEVICE

Name of the Device: OsteoVation® Impact
Common or Usual Name: Hydroxyapatite Cement
Classification Name: Methyl Methacrylate For Cranioplasty
Regulation: 882.3500
Regulatory Class: Class II
Product Code: GXP

III. PREDICATE DEVICE

510(k) Number	Product Code	Trade Name	Manufacturer
K051784 Primary	GXP	OsteoVation® CMF Bone Void Filler	Skeletal Kinetics, LLC.

IV. DEVICE DESCRIPTION

OsteoVation Impact is a self-setting, calcium phosphate bone void filler designed for single use and biocompatible. OsteoVation Impact is an impactable (moldable) calcium phosphate.

OsteoVation Impact is comprised of two working components: a calcium phosphate, a sodium phosphate (SPMA), carboxymethylcellulose powder, a sodium silicate, sodium phosphate (SPMA) solution, and a mixing system (mixing bowl, pestle and spatula). The two working components are packaged separately and are to be mixed together by the end user prior to implantation.

OsteoVation Impact is offered in 3cc, 5cc, and 10cc sterile convenience kits. Each kit includes the two working components in combination with a mixing bowl, pestle, and spatula. It is sterilized using gamma radiation with a minimum dose of 25 kGy and a maximum dose of 50 kGy with a Sterility Assurance Level of 10^{-6}.

V. INDICATIONS FOR USE

OsteoVation Impact is a calcium phosphate bone void filler indicated for the repair or filling of neurosurgical burr holes, other cranialbone defects and craniotomy cuts with a surface area no larger than $25cm^2$. OsteoVation Impact may be used in the restoration or augmentation of bony contours of the cranialbone skeleton.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices are classified as Methyl Methacrylate for Cranioplasty, and are intended for use in cranialbone applications. In establishing substantial equivalence to the predicate device, Skeletal Kinetics, LLC evaluated the indications for use, materials, technology, and product specifications of those products. Additionally, performance testing has been completed to demonstrate that the OsteoVation Impact as a bone void filler in cranialbone applications is as safe, and effective, and performs as well as the legally marketed device. The performance testing and device comparison did not raise issues of safety or efficacy.

A formulation change is being made to the powder and liquid working components of the subject device in order optimize the utility of the device during implantation. Sodium phosphate (SPMA) is being added to the liquid component along with a ratio change. A ratio change is also being made to the powder component. This formulation change increases the room temperature range for the utility of the paste from 19°C – 21°C to 19°C – 25°C. Verification testing of the working and setting time shows the formulation change does not affect the performance characteristics of the bone void filler.

The following technological differences exist between the subject and predicate device:

- Increase in room temperature range in Instructions for Use from 19°C – 21°C to 19°C – 25°C
- Addition of sodium phosphate (SPMA) to liquid component
- Ratio change to powder component

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

No biocompatibility studies were needed to demonstrate safety and efficacy.

Bench Testing

The following bench testing was conducted:

- Working time and Setting Strength
- Tensile Strength
- Temperature Profile
- pH Profile
- FTIR analysis
- Crystallographic Analysis

Test equipment

Osteovation Impact was used as indicated in Instructions for Use, Constant Temperature Water Bath (VWR, S. San Francisco, CA), Phosphate buffered saline (Sigma Chemical Co, St. Louis), Flat Plastic Spatula (Nunc, Rochester, NY), Vortexer (VWR, S. San Francisco, CA) , Mechanical Testing Machine with high load indentor (Instron, Canton, MA), Setting Test containers: Acetal (or other rigid plastic) block molds, pH meter and probe (Corning model 530 meter, model 576156 probe Corning N.Y.), Rigaku Ultima IV XRD, FTIR Spectrometer (Thermo Nicolet, Madison, WI).

Test	Test Method Summary	Results
Working time	Tests were performed to determine the workability time of the cement. Measurements included mixing and molding of the paste.	All samples passed the targeted working time and setting strength. The test results demonstrated working time comparable to the predicate device.
Setting Time	Testing was conducted to determine the Setting strength (Mean ≥450N and ≥700N) at various time points in a target temperature solution, post-sterilization after a target working time.	All samples passed the targeted setting time. The test results demonstrated setting time comparable to the predicate device.
Tensile Strength	Testing evaluated the subject	PASS

Test	Test Method Summary	Results
	device minimum tensile strength at 24 hours. Samples were prepared through the mortal/pestle combination into molds in varying diameters and thickness. Samples were placed in a prepared solution at 37°C for 24 hours. Tensile strength testing is conducted using a mechanical testing system.	The test results demonstrated tensile strength comparable to the predicate device.
Temperature Profile	The subject device is mixed and placed into a centrifuge tube and into a 37°C water bath. The temperature profile is recorded at specified intervals using a computer controlled thermocouple for 24 hours.	PASS The test results demonstrated temperature profile comparable to the predicate device.
pH Profile	The subject device is placed is mixed and placed into a centrifuge tube and into a 37°C water bath. The pH is recorded at specified intervals using a calibrated probe with a TC temperature compensator. The test evaluates physiological characteristics of the device.	PASS The test results demonstrated pH profile comparable to the predicate device
FTIR Analysis	Mix and incubate subject device for 24 hours. Dry cured sample at 37°C for 72 hours. Perform 64 scans at typical resolution of 4cm-1. This test determines the formation of hydroxyapatite.	PASS FTIR analysis show nearly identical hydroxyapatite structure as the predicate device
Crystallographic Analysis	Analyze prepared sample using x-ray diffractometer (XRD). Perform Rietveld analysis determine ratios of each compound in cured cement.	PASS XRD analysis show comparable results as the predicate device.

Animal Study

No animal studies were needed to demonstrate safety and efficacy.

Clinical Studies

No clinical studies were needed to demonstrate safety and efficacy.

VIII. CONCLUSIONS

The indication for use, technological characteristics, materials, technology, and product specifications are equivalent. The performance testing conducted, demonstrate that the OsteoVation Impact as a bone void filler in cranialbone applications is as safe, and effective, and performs as well as the legally marketed device and did not raise new issues of safety or efficacy.

Differences in the subject and predicate device formulation change increases the room temperature range for the utility of the paste. Verification testing of the working and setting time shows the formulation change does not affect the performance characteristics of the bone void filler

Additional non-clinical evaluations (tensile strength, temperature profile, pH profile, FTIR analysis, crystallographic analysis) demonstrate comparable results as the test performed for the predicate device.

The conclusions drawn from the nonclinical demonstrate that the device is as safe, and effective, and performs as well as the legally marketed device.