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

September 15, 2014

Zavation LLC
Mr. John Walker
Engineering Manager
400 Liberty Park Drive
Flowood, Mississippi 39232

Re: K141419
Trade/Device Name: ZVplasty
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX, GAA
Dated: June 30, 2014
Received: July 3, 2014

Dear Mr. Walker:

This letter corrects our substantially equivalent letter of September 12, 2014.

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,

Lori A. Wiggins -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)*
K141419

Device Name
ZVplasty

Indications for Use *(Describe)*
The Zavation ZVplasty (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

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)*

510K Summary

Date:	Aug 20, 2014
Submitter:	Zavation LLC 400 Liberty Park Drive Flowood, MS 39232 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	John Walker
Type of 510(k) submission:	Traditional
Trade name:	ZVplasty
Common Name:	Accessories for Inflatable Bone Tamp
Classification regulation/code:	888.1100, HRX 888.3027, NDN
Subsequent Product Code	878.4800, GAA
Classification name:	Arthroscope
Device classification:	Class II
Classification Panel:	Orthopedic
Basis for submission:	New device

Device Description:
The Zavation ZVplasty system is designed for use in vertebroplasty procedures for treatment of vertebral compression fractures in the lumbar or thoracic regions brought on by primary or secondary osteoporosis, cancer or trauma. The Zavation ZVplasty system consist of a variety of manual instruments which provide physicians with a means to access the vertebral body with a mechanical device in order to prepare a site for vertebroplasty. Once the site is prepared the Zavation ZVplasty system instruments are used to percutaneously deliver polymethylmethacrylate (PMMA) bone cement to the spine. The Zavation ZVplasty system instruments are to be used with the following previously FDA cleared items, balloon catheter, inflation syringe, vacuum syringe, stopcock, PMMA bone cement, cement mixing system.

Intended Use:
The Zavation ZVplasty (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Predicate Device:
CareFusion, AVAmax Vertebral Balloon (K131820)
Stryker, iVas 2-10 Balloon Catheter (K093419)

Technological Characteristics:
The Zavation ZVplasty system possesses the same technological characteristics as the predicate. These include: basic design (size), material (stainless steel), and intended use (as described above). Both the ZVplasty system and the predicate contain the following instruments: diamond tip and bevel tip introducers, drill, biopsy needle, and cement cannula. The Zavation ZVplasty system introducer cannulas have detachable handles whereas the predicates have a permanently mounted handle. The detachable handle provides the physician the choice of removing the handle for unobstructed viewing during the procedure or leaving the handle attached as would be if the handle were permanently attached. The added option for removing the handle of the introducer does not raise new issues of safety or efficacy.

Non-clinical Test:
No clinical tests were submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence because the technological performance characteristics of the subject system are the same as the predicates device.

Non-clinical Data:
The Stainless Steel, which is the only patient contacting material, and contacts the patient in a limited use is in conformance with ASTM A276 and ASTM F899. FDA Standards Recognition Number 8-343.
The luer lock connection that is molded as part of the plastic handles is in conformance with ISO 594/1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements. FDA Standards Recognition Number 6-11.
The luer lock connection that is molded as part of the plastic handle is in conformance with ISO 594-2 Second edition 1998-09-01, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings. FDA Standards Recognition Number 6-129.

The following standards apply to the sterilization of the finished device.
ISO 11135-1, Sterilization of health care products - Ethylene Oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. FDA Recognition Number 14-331.
ISO 10993-7, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals. FDA Recognition Number 14-335.
ISO 11607-1:2006, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems. FDA Recognition Number 14-355
ASTM F1929-12 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration". FDA recognition number 14-378.

Conclusion:
Based on the similarities in materials, design, principles of function, intended use and indications, the Zavation ZVplasty system has been shown to be substantially equivalent to the predicate device. Both systems contain instruments for gaining access to the vertebral body and for delivering previously cleared cement. Non-clinical data demonstrates the ZVplasty system is as safe, effective, and performs as well as the predicate device. The added option for removing the handle of the introducer does not raise new issues of safety or efficacy.