



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Osseon LLC
Mr. Keith Burger
Director of Research and Development
2330 Circadian Way
Santa Rosa, California 95407

April 9, 2015

Re: K150607

Trade/Device Name: Osseoflex SB
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: March 6, 2015
Received: March 10, 2015

Dear Mr. Burger:

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" (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 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

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

Indications for Use

510(k) Number *(if known)*
K150607

Device Name
Osseoflex SB

Indications for Use *(Describe)*

The Osseoflex® SB is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements for use during percutaneous vertebral augmentation, 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)*

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
PRASStaff@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."



9.0 510(K) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

I. SUBMITTER

Osseon LLC
2305 Circadian Way
Santa Rosa, CA 95407

Phone: 707-636-5940
Fax: 707-636-5941

Contact Person: Keith Burger, Director of Research and Development
Date Prepared: April 7, 2015

II. DEVICE

Name of Device: Osseoflex SB
Common or Usual Name: Inflatable Bone Tamp
Classification Name: Primarily – Arthroscope; Secondarily – Cement, Bone Vertebroplasty
Regulatory Class: Class II per 21CFR §888.1100; Class II per 21CFR §888.3027
Product Code: NDN; HRX

III. PREDICATE DEVICE

Osseoflex SB, 10 Gauge K141930, August 21, 2014

IV. DEVICE DESCRIPTION

The Osseoflex[®] SB is designed for use in balloon kyphoplasty. The balloon serves to create a cavity in the vertebral body, thereby reducing the fracture while still allowing for cement interdigitation. The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon catheter provides a conduit through which the physician can inflate the balloon at the distal end of the catheter. After the bone is disrupted, PMMA is injected through an Osseoflex[®] needle to fill the previously created void(s).

An access channel is required for Osseoflex[®] SB placement. The Osseoflex[®] SB device does not create an access channel; the Osseoflex[®] SB is designed to follow a pre-existing channel created by an access channel device.



V. INDICATIONS FOR USE

The Osseoflex[®] SB is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements for use during percutaneous vertebral augmentation, such as kyphoplasty.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Summary of Technological Characteristics of the Additional Size Compared to the Current Size (Predicate)				
Characteristic	Line Extension		Current Size (Predicate)	
Trade Name, Model	Osseoflex SB, OT-0224	Osseoflex SB, OT-0222	Osseoflex SB, OF-0224	Osseoflex SB, OF-0222
Cannula size	10G			
Max inflation volume	4ml	2ml	4ml	2ml
Balloon Inflation Medium	60% Contrast			
Balloon Material	Polyurethane			
Balloon Diameter at nominal volume	18 mm	14 mm	18 mm	14 mm
Balloon Length at nominal volume	21 mm	14 mm	21 mm	14 mm
Balloon Shape	Cylindrical	Spherical	Cylindrical	Spherical
Max inflation pressure	400 psi (27 ATM)			
Device Modification	Straight Stylet	Straight Stylet	Steerable Stylet	Steerable Stylet

The overall materials, specifications and manufacturing processes for the current device to the line extension device have not changed.

The only difference is the replacement of the steerable stylet in the current device with a straight stylet in the modified device.

VII. PERFORMANCE DATA

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

Bench Tests Performed	Acceptance Criteria
Balloon Profile and Tamp (Catheter) Working Length	<ul style="list-style-type: none"> Balloon profile ≤ 2.79 mm (0.109 in) Balloon catheter working length > 16.5 cm



(TM-003)	
Balloon Compliance (TM-004):	<ul style="list-style-type: none"> Balloon working length (L) \leq 24 mm Balloon diameter (D) \leq 19 mm
Maximum Pressure (TM-006)	The inflatable bone tamp exceeds the maximum inflation pressure, 27 atm (~400 psi) without failure.
Bond Tensile Strengths (TM-007)	Bond tensile strength \geq 15 N (3.37 lbf). The tensile force specification was adopted directly from ISO 10555 (Single Use Intravascular Catheters) requirements. This tensile force maybe applied to the device during use when the balloon is deflated and retracted back through the access cannula.
Balloon Maximum Volume (TM-008)	Maximum inflation volume to be greater than the maximum recommended volume with 95% confidence and 90% reliability.
Balloon Fatigue, Unconstrained (TM-009)	Inflate to maximum recommended volume of, hold for 30 seconds / deflate; without leaks for 20 cycles.
Balloon Inflation, Deflation Time (TM-010)	Deflation times to be $<$ 5 seconds with 90/90% confidence/ reliability.

VIII. CONCLUSION

The results of the non-clinical tests show that the Osseoflex SB, 10 Gauge Straight Balloon meets or exceed all performance requirements, and are substantially equivalent to the predicate device.