August 30, 2018

Vexim SA
% Ms. Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K181262
Trade/Device Name: SpineJack® Expansion Kit
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: August 3, 2018
Received: August 3, 2018

Dear Ms. Hogan:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181262

Device Name

SpineJack® Expansion Kit

Indications for Use *(Describe)*

The SpineJack® Expansion Kit is indicated for use in the reduction of painful osteoporotic vertebral compression fractures. It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cements.

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

Prepared:

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II. DEVICE

Name of Device:	SpineJack Expansion Kit
Common/Usual Name:	Implantable Fracture Reduction System
Regulation Numbers:	21 CFR 888.3027
Regulation Name:	Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class:	II
Product Codes:	NDN, Cement, Bone, Vertebroplasty

III. PREDICATE DEVICE

Primary Predicate	Kiva® VCF Treatment System, K132817
Reference Device	StaXx™ FX System, K053336
Reference Device/Clinical Comparator	Kyphon KyphX Xpander® Inflatable Bone Tamp, K041454

510(k) Summary

IV. DEVICE DESCRIPTION

The SpineJack Expansion Kit (herein referred to as "SpineJack") is an implanted fracture reduction system, intended to reduce vertebral compression fractures. The SpineJack Expansion Kit is used with the Preparation Kit. The Expansion Kit is available in three sizes, to accommodate different vertebral body sizes, Ø4.2mm, Ø5mm, and Ø5.8mm. After the SpineJack implant is inserted, it is expanded, and PMMA bone cement is injected at a low pressure to stabilize the restored vertebral body. The bone cement and its delivery system are intended to be used with the SpineJack, but are sold separately.

V. INDICATIONS FOR USE

The SpineJack Expansion Kit is indicated for use in the reduction of painful osteoporotic vertebral compression fractures. It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cement.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table identifies technological characteristics shared between the predicate and subject device:

Table 1: Comparison of Technological Characteristics with Predicate Device

Element of Comparison	SpineJack (subject device)	Kiva® VCF Treatment System (K132817) Primary Predicate
Classification	Class II	Class II
Regulation	21 CFR 888.3027	21 CFR 888.3027
Product Code	NDN	NDN
Indications	The SpineJack Expansion Kit is indicated for use in the reduction of painful osteoporotic vertebral compression fractures. It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cement.	The Kiva® VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

510(k) Summary

Contact	Implantable	Implantable
Material	Ti-6Al-4V with PMMA (cement injected)	Nitinol and PEEK with PMMA (cement injected)
Length, mm	14 – 20 (plate length)	20 (diameter)
Width, mm	4 - 6	Not applicable
Height (pre and post expansion), mm	4 - 20 (Surgeon determined)	Up to 15 mm
Expansion mechanism	Plastic deformation of struts, continuous	Deployment of the system over nitinol wire loop
Number of Implants Typically Used	1-2 per patient	1

Both the SpineJack and the predicate are implants intended for use in conjunction with cement for vertebral compression fractures. Although the devices differ in materials, the key questions of whether the materials are biocompatible and provide appropriate mechanical strength for this indication are applicable to both devices; no new questions are raised. In addition, appropriate biocompatibility, mechanical, and clinical testing has been performed to confirm that these differences do not adversely impact performance. Similarly, although the specific mechanism of device expansion differs for the SpineJack compared to the predicate, the key questions related to device expansion in vivo are the same for both devices, i.e., does the expansion mechanism provide adequate strength to create the desired lifting force without exerting excessive force on the vertebral endplate. In addition, bench and clinical testing confirm that the expansion mechanism of the SpineJack is appropriate for its intended use and functions as intended. Thus, a conclusion of substantial equivalence is supported.

VII. PERFORMANCE TESTING

The following performance testing was conducted to support substantial equivalence:

Performance Testing

Mechanical and functional testing was performed to verify the design of the implant, including:

- Pushing and Recompression Testing
- Crimp Force Testing
- Traction Resistance Testing
- Torsion Testing

510(k) Summary

- VertaPlex HV (PMMA cement) and AutoPlex (cement mixer) Functional Test with SpineJack Implant
- VertaPlex HV and PCD (cement mixer) Functional Test with SpineJack Implant
- VertaPlex HV and AutoPlex with Hand Obturation Functional Test with SpineJack Implant

Biocompatibility

Biocompatibility testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."

The SpineJack implant was also tested to be non-pyrogenic.

Sterility

Sterilization validation testing was performed in accordance to ISO 11137-1:2006 "Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices."

MR Compatibility

Non-clinical testing demonstrated that the SpineJack implant range is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 18,000-Gauss/cm (extrapolated)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the SpineJack implant range is expected to produce a maximum temperature rise of 2.1˚C after 15-minutes of continuous scanning (i.e., per pulse sequence) when using an MR system incorporating a quadrature transmit/receive RF body coil.

510(k) Summary

In non-clinical testing, the image artifact caused by the SpineJack implant range extends approximately 10-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Clinical Studies

The pivotal study of the SpineJack was designed to compare the safety and effectiveness of the device with the KyphX Xpander Inflatable Bone Tamp (balloon kyphoplasty or BKP) for use to treat patients with painful VCFs due to osteoporosis. The study enrolled 152 patients at 13 active sites in 5 different European countries, including France, Germany, Italy, Spain, and Switzerland. Subjects were randomized to treatment with the SpineJack or BKP in a 1:1 ratio. The study followed patients for 12 months after surgery.

In accordance with FDA guidance, the baseline characteristics of patients enrolled in the clinical study were compared between groups, as well as to populations enrolled in other similar US studies of the same indication. The percent of female patients was similar between groups, 75% for the SpineJack and 82% for the control group. The mean age was also similar between groups (74 for SpineJack, 72 for the control). Baseline severity in terms of both pain and function were also similar between groups. The above characteristics are consistent with the US osteoporosis population with vertebral fractures, which is predominantly female and with a mean age in the 70s. With regard to concomitant diseases, more than half patients in each group suffered from hypertension (60.3% in the SpineJack® group; 56.2% in the BKP group); 25.0% of patients from the SpineJack® group and 20.5% of patients from the BKP group presented with another cardiovascular pathology. The patient accountability rate was also very similar between groups, approximately 90% for both groups at 6 and 12 months, mitigating the potential for bias related to differential loss to follow-up.

In addition to comparison between study groups, because the SAKOS study was conducted in Europe, to evaluate applicability of the data to the US population, the demographics and baseline characteristics of the SAKOS study population were also compared to the characteristics of corresponding U.S. populations reported in the literature. Compared to the two most recent prospective kyphoplasty studies performed in the U.S. and enrolling at least 150 patients, Beall et. al. (EVOLVE), and Dohm et al. (KAVIAR), all demographic and baseline clinical characteristics were very similar across

510(k) Summary

investigations. Outcomes in terms of pain and function were also very similar to other US studies reported in the literature. The SAKOS study was recruited from a multinational population, with centers in Switzerland, Spain, Germany, France and Italy. Although EU regulations do not permit collection of race or ethnicity data, the international nature of the study population provides a broad cross-section of patients that is representative of the intended use population. In addition, the similarity of the overall population in terms of baseline characteristics (age, sex, baseline pain and function) to other populations reported in US studies in the published literature also support that the data is applicable to the United States. The SpineJack has also been commercially distributed internationally in 12 countries, including use in Europe, Asia, Africa, and South America, further supporting its applicability to a broad and representative patient population.

Thus, although the SAKOS study was performed in Europe, the final study population was very similar to what has been reported in the literature for U.S.-based studies of kyphoplasty, and the outcomes of the investigation were also consistent with other studies performed in US populations for the same indication.

The primary analysis compared the 12-month responder rate of the SpineJack device to the predicate BKP, where a responder was defined to require clinically meaningful improvement in pain and function without pre-specified serious adverse events or reinterventions. The results of the final study analysis at the 12 month timepoint demonstrated strong results, meeting the criteria for study success. The final study analysis demonstrated a 12-month responder rate of 89.8% in the SpineJack group compared to 87.3% in the BKP group ($p=0.0016$). The posterior probability for the final Bayesian analysis (0.09969) successfully met the criteria for study success (posterior probability > 0.987) and demonstrated non-inferiority of the SpineJack to the predicate BKP.

Assuming the primary endpoint analysis was successful, the Statistical Analysis Plan prospectively defined superiority testing for an additional composite endpoint that added a fourth component (“absence of adjacent level fractures”). Using that composite endpoint the responder rate at Month 12 in the ITT population was significantly higher

510(k) Summary

for patients that underwent the SpineJack procedure compared to BKP (79.7% versus 59.3% respectively, p<0.0001), meeting the criteria necessary to establish superiority. Given that the primary analysis and additional composite endpoint analyses were successful, midline target height restoration was also tested for superiority versus BKP. In the ITT population, the restoration obtained with SpineJack® procedure at 12 months was significantly more marked than with BKP (1.31 ± 2.58 mm vs 0.10 ± 2.34 mm; median: 1.00 vs 0.30 mm; p=0.0035). Thus, the results of the study demonstrated non-inferiority to balloon kyphoplasty with respect to overall success, and superiority to balloon kyphoplasty for the additional composite endpoint of success with freedom from adjacent fracture, and midline vertebral height restoration.

Both groups also showed substantial and sustained improvement in both VAS pain and function as measured by the Oswestry Disability Index (ODI). In the SpineJack group. the mean VAS score and ODI score improved to a low 15.7 and 13.4, respectively, at 12-months. This represents an absolute change from baseline of -62.1 for the mean VAS and -51.1 for the mean ODI.

The study results also demonstrated the safety profile of the SpineJack, which was similar to that of BKP. Both treatment groups had similar rates of cement extravasation, subsequent vertebral fractures, and adverse events. The SpineJack group demonstrated a significantly lower incidence of adjacent fractures. The BKP group also experienced non-adjacent subsequent thoracic vertebral fractures at a rate that was nearly three times that in the SpineJack group. The SpineJack group also demonstrated fewer instances of osteolysis/osteonecrosis (4 patients (5.9%) versus 9 patients (12.5%)). While the BKP group experienced 2 cases of device deficiency (2.7%) (balloon rupture), the SpineJack group did not experience any device deficiencies/malfunctions.

In sum, the study results demonstrated that the SpineJack performs in a manner that is substantially equivalent to the predicate device, with a strong safety profile and very positive pain and function improvement. These results were consistent with prior studies outside the United States in over 300 subjects, which also supported safety and performance. The results support the finding of substantial equivalence to the predicate device.

510(k) Summary

VIII. CONCLUSIONS

The differences that exist between SpineJack and its predicate do not raise different questions of safety or effectiveness. The results of clinical and performance testing demonstrate that the SpineJack will perform safely as intended and support a determination of substantial equivalence to the predicate device which is marketed for the same intended use.