December 20, 2022

Stryker Instruments
Bruce Backlund
Principal Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K223294
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: October 25, 2022
Received: October 26, 2022

Dear Bruce Backlund:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sara S. Thompson -S

For

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223294

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, traumatic vertebral compression fractures (Type A fractures according to the AO/Magerl classification) with or without posterior instrumental fixation, and compression fractures that result from malignant lesions (myeloma or osteolytic metastasis). It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cement.

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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Contact

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Date Prepared: 19 December 2022

I. Devices

Brand Name: SpineJack® Expansion Kit
Common Name: Implantable Fracture Reduction System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: II
Product Code: NDN - Cement, Bone, Vertebroplasty

II. Predicate Devices

SpineJack® Expansion Kit, K211238

The predicate has not been subject to a design-related recall, and no reference devices were used in this submission.

III. Device Description

The SpineJack® Expansion Kit ("SpineJack") is an implanted reduction system intended to reduce vertebral compression fractures. The SpineJack is used with a Preparation Kit (sold separately) which prepares the vertebra for implant. The SpineJack is available in three sizes to accommodate different vertebral body sizes, specifically 4.2 mm, 5 mm, and 5.8 mm. After the implant is inserted, it is expanded to reduce the vertebral compression fracture and Vertaplex Radiopaque Bone Cement, or Vertaplex HV Radiopaque Bone Cement (sold separately) is injected at low pressure to fixate the restored vertebral body.

IV. Proposed Indications for Use, Contraindications

Indications for Use:

SpineJack® Expansion Kit

The SpineJack® Expansion Kit is indicated for use in the reduction of painful osteoporotic

vertebral compression fractures, traumatic vertebral compression fractures (Type A fractures according to the AO/Magerl classification) with or without posterior instrumental fixation, and compression fractures that result from malignant lesions (myeloma or osteolytic metastasis). It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cement.

Contraindications:

The SpineJack device is not indicated for any application other than that for which the device is designed.

The list of contraindications given below is not limited. Refer to the instructions for use of the PMMA cement used in combination with the SpineJack implant.

- Patient presenting with non-mobile fractures
- Sclerotic fracture or fracture not showing a pseudarthrosis
- Patient with a prior history of intolerance or of allergic reaction to titanium and/or one of the components of the PMMA cement
- Patient suffering from irreversible coagulopathy or undergoing anticoagulant treatment at the time of surgery or at least 8 days prior to inclusion
- Active infection (systemic or in the target vertebra)
- Patient suffering from a severe or uncontrolled systemic disease
- Patient presenting neurological damage caused by vertebral fracture
- Patient pregnant or likely to be so or breastfeeding
- Patient vertebral anatomy not compatible with the size of the implant or instrumentation
- Fracture geometry making the insertion of the implant impossible
- Patients presenting with type B or C traumatic vertebral fractures according to the Magerl classification

V. Comparison with Predicate Device

The modification to the SpineJack concern the indications for use and resulting labeling only. No modifications were required of the physical device. Therefore, mechanical design, materials, sizes, packaging, sterilization, user profile, and use environment are identical.

Element of Comparison	**SpineJack Expansion Kit (SpineJack) Subject Device**	**SpineJack Expansion Kit (SpineJack) Predicate Device K211238**	**Comparison**
Regulatory Information Comparison			
Classification	Class II	Class II	Identical
Regulation	21 CFR 888.3027	21 CFR 888.3027	Identical
Product Code	NDN	NDN	Identical
Panel	Orthopedic	Orthopedic	Identical
Intended Use and Indications for Use Comparison			
Intended Use	Intended for the reduction of vertebral compression fractures	Intended for the reduction of vertebral compression fractures	Identical

Indications for Use	The SpineJack Expansion Kit is indicated for use in the reduction of painful osteoporotic vertebral compression fractures, traumatic vertebral compression fractures (Type A fractures according to the AO/Magerl classification) with or without posterior instrumental fixation, and compression fractures that result from malignant lesions (myeloma or osteolytic metastasis). It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cement.	The SpineJack Expansion Kit is indicated for use in the reduction of painful osteoporotic vertebral compression fractures, and traumatic vertebral compression fractures (Type A fractures according to the AO/Magerl classification) with or without posterior instrumental fixation. It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cement.	Different – additional indication for compression fractures that result from malignant lesions (myeloma or osteolytic metastasis)
Contraindications	▪ Patient presenting with non-mobile fractures ▪ Patients presenting with Type B or C traumatic vertebral fractures according to the Magerl Classification. ▪ Sclerotic fracture or fracture not showing a pseudarthrosis ▪ Patient with a prior history of intolerance or of allergic reaction to titanium and/or one of the components of the PMMA cement ▪ Patient suffering from irreversible coagulopathy or undergoing anticoagulant treatment at the time of surgery or at least 8 days prior to inclusion ▪ Active infection (systemic or in the target vertebra) ▪ Patient suffering from a severe or uncontrolled systemic disease ▪ Patient presenting neurological damage caused by vertebral fracture ▪ Patient pregnant or likely to be so or breastfeeding ▪ Patient vertebral anatomy not compatible with the size of the implant or instrumentation ▪ Fracture geometry making the insertion of the implant impossible	▪ Patient presenting with non-mobile fractures ▪ Patients presenting with Type B or C traumatic vertebral fractures according to the Magerl Classification. ▪ Patients presenting with tumoral fractures ▪ Sclerotic fracture or fracture not showing a pseudarthrosis ▪ Patient with a prior history of intolerance or of allergic reaction to titanium and/or one of the components of the PMMA cement ▪ Patient suffering from irreversible coagulopathy or undergoing anticoagulant treatment at the time of surgery or at least 8 days prior to inclusion ▪ Active infection (systemic or in the target vertebra) ▪ Patient suffering from a severe or uncontrolled systemic disease ▪ Patient presenting neurological damage caused by vertebral fracture ▪ Patient pregnant or likely to be so or breastfeeding ▪ Patient vertebral anatomy not compatible with the size of the implant or instrumentation ▪ Fracture geometry making the insertion of the implant impossible	Similar- The subject device is proposing the removal of: Patients presenting with tumoral fractures as they don't meet the definition of a contraindication and this submission is seeking a cleared indication for tumoral fractures (i.e. fractures caused by malignant lesions such as myeloma or osteolytic metastasis).

Cement for Use with Implant	Intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cements	Intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cements	Identical
Technological Comparison			
Contact	Implantable	Implantable	Identical
Fundamental Scientific Technology	The Expansion Kit consists of the SpineJack implant and an implant expander. The implant is composed of a deformable element and a locking tube and is made from a titanium alloy.	The Expansion Kit consists of the SpineJack implant and an implant expander. The implant is composed of a deformable element and a locking tube and is made from a titanium alloy.	Identical
Principal of Operation	The SpineJack is implanted into the vertebra after access is established and the site is prepared for the implant. It is inserted into the vertebra via the pedicle in a collapsed form, and expanded in situ, to achieve reduction of vertebral compression fractures. Once inserted and expanded, PMMA bone cement is injected into the space around the SpineJack to maintain the fracture reduction.	The SpineJack is implanted into the vertebra after access is established and the site is prepared for the implant. It is inserted into the vertebra via the pedicle in a collapsed form, and expanded in situ, to achieve reduction of vertebral compression fractures. Once inserted and expanded, PMMA bone cement is injected into the space around the SpineJack to maintain the fracture reduction.	Identical
Plate Length (mm)	14/19/20	14/19/20	Identical
Total Length (mm)	20/25/28	20/25/28	Identical
Height Pre-Expansion (mm)	4.2/5.0/5.8	4.2/5.0/5.8	Identical
Maximum Height Post-Expansion (mm)	12.5/17/20	12.5/17/20	Identical
Implant Material	Ti-6Al-4V	Ti-6Al-4V	Identical

VI. Performance Data

No bench or biocompatibility testing was required to support the proposed indications. Additionally, no prospective clinical data was generated for the purpose of supporting this submission. The proposed indications are supported by clinical data collected from Literature and Real-World Evidence (RWE).

Literature summary: Relevant publications were thoroughly analyzed to determine the safety and effectiveness of the SpineJack system for use for treatment of malignant, spinal bone tumors. The literature shows that the safety profile for SpineJack/cement for use in painful osteoporotic VCFs, traumatic VCFs and malignant lesions (myeloma or osteolytic metastasis) VCFs is nearly the same. No different types of adverse events are seen in malignant lesions (myeloma or osteolytic metastasis) as compared to trauma or osteoporosis, and those adverse events that they have in common (cement leakage) occur at similar rates. All potential risks were noted and evaluated specifically with regard to an acceptable benefit/risk ratio. Across all studies there was statistically significant pain improvement with sustained long-term relief as measured by the Visual Analogue Scale (VAS). This decrease in pain occurred regardless of the treatment details or concomitant procedures performed and was found to persist for up to 5 years after the initial

treatment. It was found in these studies that the SpineJack system can not only reduce pain but also improve the quality of life for this patient cohort demonstrated by the EQ5 VAS and Oswestry Disability Index. The data demonstrated that the SpineJack system is an effective treatment option, notably for pain relief, in treating malignant spinal tumors.

Patient Demographics: The studies provided evidence on 304 patients who received SpineJack System, of which 117 were treated for malignant vertebral fractures. These studies took place in Spain, France, Switzerland and in the United States. The age range of patients was between 23 to 90 years of age with the mean age in all studies recorded above 62 years. Of the 304 patients 136 were male (45%) and 166 (55%) were female. Body mass index was recorded in two studies as 26.0 ± 4.6 kg/m2 and 28.8 ± 5.8kg/m2. The one study in the United States reported on ethnicity with 70% of the study being Caucasian, and the ethnicity of the remaining 30% was not documented. EU regulations do not permit collection of race or ethnicity data however, no race or ethnic group were excluded based on exclusion criteria in any study. Fractures were located from T6 to L4, with the thoracolumbar junction the most affected area. The patients had a wide range of primary tumor locations including but not limited to breast, lung, ovarian, kidney, melanoma and gastrointestinal.

VII. Conclusion

The evidence provided within this submission supports that the proposed indications are a subset of the intended use of the predicate (reduction/fixation of vertebral compression fractures), just as the predicate indications painful osteoporotic vertebral compression fractures, and traumatic vertebral compression fractures (Type A fractures according to the AO/Magerl classification) with or without posterior instrumental fixation are a subset of the intended use. Therefore, the subject device has the same intended use as the predicate.

The characteristics described above in the Performance Data section are consistent with the US malignant, spinal bone tumor population. The average age of patients affected by secondary spinal tumors is 55 – 60 years[1]. Furthermore, many of the primary tumors mentioned above affect persons of increased age, with 60% of cancer patients over 65 years of age[2] which is in line with the population captured here. Additionally, the information from these studies does include information on a patient cohort from the United States. This study included 30 patients (n=19 for tumor indication) of which 12 patients were male and 18 were female, with a mean age of 62.7 (±12.8) and fractures located from T7 to L4, with most fractures occurring at T12 and L1.

United States census population estimates in July 2021 reported that more than 70% of Americans are in the ethnic group of "White alone"[3]. In the 2010 census more than 70% of Americans were in the ethnic group of "White/ Caucasian Americans"[4]. According to U.S. Office of Management and Budgets, "White" refers to a person having origins in any of the original peoples of Europe, the Middle East, or North Africa[4]. The EU Statistics on migration to Europe (2022) reports that 5.3% of all residents come from outside the European Union (EU) and 8.4% of residents were born outside of the EU[5], further demonstrating that the current EU

population is not homogeneous. Therefore, any clinical data stemming from the European population are fully transferrable to the American population.

The RWE provided demonstrates that there are not different types of questions related to safety or effectiveness when SpineJack/cement are used for reduction/fixation of malignant lesions (myeloma or osteolytic metastasis) VCFs. The literature shows that the safety profile for SpineJack/cement for use in painful osteoporotic VCFs, traumatic VCFs and malignant lesions (myeloma or osteolytic metastasis) VCFs is nearly the same. No different types of adverse events are seen in malignant lesions (myeloma or osteolytic metastasis) as compared to trauma or osteoporosis, and those adverse events that they have in common (cement leakage) occur at similar rates. The subject devices are safe and effective for their intended use and indications for use.

The intended use is the same as the predicate, and the difference in indication does not pose different questions of safety or effectiveness. The proposed devices are at least as safe and effective as the predicate devices for the proposed indications. The technological characteristics are identical between subject and predicate, as no physical design changes were required to allow for use in malignant lesions (myeloma or osteolytic metastasis) vertebral compression fractures. Therefore, a decision of substantial equivalence is supported.

References:

1. Greenlee RT, Murray T, Bolden S, Wingo PA. Cancer statistics, 2000. CA Cancer J Clin. 2000 Jan-Feb;50(1):7-33. doi: 10.3322/canjclin.50.1.7. PMID: 10735013
2. SEER Cancer Statistics Review 1975–2000, National Cancer Institute. Retrieved from https://seer.cancer.gov/archive/csr/1975_2000/
3. Retrieved from https://www.census.gov/quickfacts/fact/table/US/PST045221. Accessed on December 13th, 2022.
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5. Retrieved from https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/statistics-migration-europe_en Accessed on December 14th, 2022