October 20, 2020

Stryker Corporation
Kristi Ashton
Senior Staff RA Specialist
1926 Stryker Way
Kalamazoo, Michigan 49002

Re: K202393
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 18, 2020
Received: August 21, 2020

Dear Kristi Ashton:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202393

Device Name

SpineJack® Expansion Kit (Spinejack ®)

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 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.

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."

stryker

510(K) SUMMARY

510(K) SUMMARY: SPINEJACK® EXPANSION KIT	
Submitter:	Stryker Instruments 1941 Stryker Way Kalamazoo, MI 49002 USA
	Contact Name: Kristi Ashton Title: Senior Staff RA Specialist Phone: 269-800-1692 E-mail: Kristi.Ashton@Stryker.com
Date prepared:	October 20, 2020
Subject Device Trade Name:	SpineJack Expansion Kit (SpineJack)
Common Name:	Implantable Fracture Reduction System
Classification Name:	Cement, Bone, Vertebroplasty
Product Code:	NDN
Regulatory Class:	II
Regulation Name:	Polymethylmethacrylate (PMMA)
Regulation Number:	21 CFR 888.3027
Predicate Device:	SpineJack Expansion Kit (SpineJack), K181262
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 a validated Stryker PMMA bone cement, such as Stryker VertaPlex® or VertaPlex® HV 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.
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.
Non-Clinical Testing	Non-clinical testing was deemed not required for this 510(k). The SpineJack implant was previously tested to be non-pyrogenic.
Clinical Testing	Clinical testing was deemed not required for this 510(k)
Other Evidence:	Clinical literature, post-market surveillance data and a risk analysis per ISO 14971 were used in support of the subject modification.
Summary of Technological Characteristics **Table 1** below details the comparisons between the subject and predicate devices.	

stryker

Table 1 Comparison of Regulatory and Technical Characteristics

Element of Comparison	SpineJack Subject Device	SpineJack Predicate Device	Comparison
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 cements.	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.	Identical
Contraindications	Patients presenting with type B or C traumatic vertebral fractures according to the Magerl classification.	Patient presenting with traumatic fractures (Reference IFU for full list of contraindications)	Different-It is proposed that Type A trauma fractures are removed from the list of contraindications for SpineJack. Clinical literature, post-market data and a risk assessment per ISO 14971 were provided to support the safety of this modification. This change does not raise new types of safety and effectiveness questions regarding the use of the subject device.
Contact	Implantable	Implantable	Identical
Material	Ti-6Al-4V with PMMA (cement injected)	Ti-6Al-4V with PMMA (cement injected)	Identical
Length (mm)	14 - 20 (plate length)	14 - 20 (plate length)	Identical
Width (mm)	4 - 6	4 - 6	Identical
Height pre and post expansion (mm)	4 - 20 (Surgeon determined)	4 - 20 (Surgeon determined)	Identical
Expansion Mechanism	Plastic deformation of struts, continuous	Plastic deformation of struts, continuous	Identical
Number of Implants Typically Used	1-2 per patient	1-2 per patient	Identical

Conclusion	SpineJack has the same intended use, fundamental scientific technology, principle of operation, and mode of action as the predicate device. An evaluation of clinical literature, post-market data in US and Europe and risk per ISO 14971 provide the evidence to support the removal of Type A trauma fractures from the contraindications. The use of post-market data from Europe demonstrates the history of safe and effective use of the product in Type A traumatic fractures since 2008. The evaluation of the post-market data, use history and a clinical literature review provide established evidence which confirm that the subject modification does not raise new types of safety and effectiveness questions regarding the use of the subject device. Therefore, it is proposed that the subject SpineJack is equivalent to the predicate device.