June 25, 2021

Stryker Instruments
Susanne Galin
Senior Principal Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K211238
Trade/Device Name: SpineJack® Expansion Kit, Vertaplex® Radiopaque Bone Cement, Vertaplex® High Viscosity (HV) Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN, LOD, PML
Dated: April 24, 2021
Received: April 26, 2021

Dear Susanne Galin:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211238

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, and traumatic vertebral compression fractures (Type A fractures according to the AO/Magerl classification) with or without posterior instrumental fixation. They are 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.

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PRAStaff@fda.hhs.gov

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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)*
K211238

Device Name
Vertaplex® Radiopaque Bone Cement

Indications for Use *(Describe)*
Vertaplex® Radiopaque Bone Cement is indicated for fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with the SpineJack Expansion Kit, Vertaplex® Radiopaque Bone Cement is also indicated for the fixation of osteoporotic or traumatic AO/Magerl Type A vertebral compression fractures.

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)

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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)*
K211238

Device Name
Vertaplex® HV Radiopaque Bone Cement

Indications for Use *(Describe)*
Vertaplex® HV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with ES2® Augmentable Spinal System, Vertaplex® High Viscosity (HV) Radiopaque Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Vertaplex® High Viscosity (HV) Radiopaque Bone Cement and the ES2® Augmentable Spinal System are for use together at spinal levels where the structural integrity of the spine is not severely compromised.

When used in conjunction with the SpineJack Expansion Kit, Vertaplex® High Viscosity (HV) Radiopaque Bone Cement is also indicated for the fixation of osteoporotic or traumatic AO/Magerl Type A vertebral compression fractures.

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)

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stryker

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Contact

Susanne Galin, RAC
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Date Prepared: 24 April 2021

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

Brand Name: Vertaplex® Radiopaque Bone Cement
Common Name: PMMA Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: II
Product Code: NDN, Cement, Bone, Vertebroplasty
LOD, Bone Cement

Brand Name: Vertaplex® High Viscosity (HV) Radiopaque Bone Cement
Common Name: PMMA Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: II
Product Code: NDN, Cement, Bone, Vertebroplasty
PML, Bone Cement, Posterior Screw Augmentation

II. Predicate Devices

SpineJack® Expansion Kit, K202393

Vertaplex Radiopaque Bone Cement, K072118

Vertaplex High Viscosity (HV) Radiopaque Bone Cement, K192818

These predicates have 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

SpineJack Expansion Kit

Indications for Use:
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. They are intended to be used in combination with Stryker Vertaplex® and Vertaplex® HV Radiopaque bone cements.

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
- 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

Vertaplex Radiopaque Bone Cement

Indications for Use:
Vertaplex® Radiopaque Bone Cement is indicated for fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with SpineJack Expansion Kit, Vertaplex® Radiopaque Bone Cement is also indicated for the fixation of osteoporotic or traumatic AO/Magerl Type A vertebral compression fractures.

Contraindications:
- Allergies or sensitivity to any of its chemical components
- The presence of active or incompletely treated infection at the site where the bone cement is to be applied
- Coagulation disorders, or with severe cardiopulmonary disease
- Spinal stenosis (>20% by retropulsed fragments)
- Vertebral plana (collapse >90%)
- Compromise of the vertebral body or the walls of the pedicles
- For vertebroplasty, unstable vertebral fractures due to posterior involvement
- Patient clearly improving on medical therapy
- Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture
- For vertebroplasty, non-pathological acute traumatic fractures of the vertebra

Vertaplex HV High Viscosity Radiopaque Bone Cement

Indications for Use:
Vertaplex® HV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with ES2® Augmentable Spinal System, Vertaplex® High Viscosity (HV) Radiopaque Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving

the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Vertaplex® High Viscosity (HV) Radiopaque Bone Cement and the ES2® Augmentable Spinal System are for use together at spinal levels where the structural integrity of the spine is not severely compromised.

When used in conjunction with SpineJack Expansion Kit, Vertaplex® High Viscosity (HV) Radiopaque Bone Cement is also indicated for the fixation of osteoporotic or traumatic AO/Magerl Type A vertebral compression fractures.

Contraindications:

- Allergies or sensitivity to any of its chemical components
- The presence of active or incompletely treated infection at the site where the bone cement is to be injected.
- Coagulation disorders, or with severe cardiopulmonary disease
- Spinal stenosis (>20% by retropulsed fragments)
- Vertebral plana (collapse >90%)
- Compromise of the vertebral body or the walls of the pedicles
- For vertebroplasty, unstable vertebral fractures due to posterior involvement
- Patient clearly improving on medical therapy
- Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture
- For vertebroplasty/sacroplasty, non-pathological acute traumatic fractures of the vertebra/sacrum
- Displaced sacral fractures
- Compromise of the sacral foramina
- If sacral surgical fusion may be required

V. Comparison with Predicate Devices

The modifications to the SpineJack, Vertaplex Radiopaque Bone Cement, and Vertaplex HV Radiopaque Bone Cement 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 K202393**	**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	The SpineJack ® Expansion Kit is indicated for use in the reduction	Different –

	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. They are intended to be used in combination with Stryker Vertaplex® and Vertaplex® HV bone cement.	of painful osteoporotic vertebral compression fractures. It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cements.	Additional indication for traumatic vertebral compression fractures with or without posterior instrumental fixation.
Contraindications	▪ 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	▪ 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	Identical
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

Element of Comparison	**Vertaplex Radiopaque Bone Cement Subject Device**	**Vertaplex Radiopaque Bone Cement Predicate Device K072118**	**Comparison**
Regulatory Information Comparison			
Classification	Class II	Class II	Identical
Regulation	21 CFR 888.3027	21 CFR 888.3027	Identical
Product Code	NDN, LOD	NDN, LOD	Identical
Panel	Orthopedic	Orthopedic	Identical
Intended Use and Indications for Use Comparison			
Intended Use	Fixation of vertebral compression fractures	Fixation of vertebral compression fractures	Identical
Indications for Use	Vertaplex® Radiopaque Bone Cement is indicated for fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma). When used in conjunction with SpineJack® Expansion Kit,	Vertaplex Radiopaque Bone Cement is indicated for fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).	Different - Addition of indication for use with SpineJack for fixation of pathological or non-pathological traumatic vertebral compression fractures

	Vertaplex® Radiopaque Bone Cement is also indicated for the fixation of osteoporotic or traumatic AO/Magerl Type A vertebral compression fractures.		
Contraindications	• Allergies or sensitivity to any of its chemical components • The presence of active or incompletely treated infection at the site where the bone cement is to be applied • Coagulation disorders, or with severe cardiopulmonary disease • Spinal stenosis (>20% by retropulsed fragments) • Vertebral plana (collapse >90%) • Compromise of the vertebral body or the walls of the pedicles • For vertebroplasty, unstable vertebral fractures due to posterior involvement • Patient clearly improving on medical therapy • Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture • For vertebroplasty, non-pathological acute traumatic fractures of the vertebra	• Allergies or sensitivity to any of its chemical components • The presence of active or incompletely treated infection at the site where the bone cement is to be applied • Coagulation disorders, or with severe cardiopulmonary disease • Spinal stenosis (>20% by retropulsed fragments) • Vertebral plana (collapse >90%) • Compromise of the vertebral body or the walls of the pedicles • Unstable vertebral fractures due to posterior involvement • Patient clearly improving on medical therapy • Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture • Non-pathological acute traumatic fractures of the vertebra	Similar – Clarification that use of bone cement for vertebroplasty (using cement alone) for treatment of non-pathological acute traumatic fractures or unstable vertebral fractures due to posterior involvement are contraindicated
Technological Comparison			
Contact	Implantable	Implantable	Identical
Principal of Operation	Powder and liquid components are mixed together so that they polymerize and form a hardened acrylic polymer. The mixture is in a pourable and injectable state for a period of time, before it cures to form a hardened structure, capable of long-term load support, bone augmentation and implant encapsulation in the treatment of vertebral compression fractures.	Powder and liquid components are mixed together so that they polymerize and form a hardened acrylic polymer. The mixture is in a pourable and injectable state for a period of time, before it cures to form a hardened structure, capable of long-term load support, bone augmentation and implant encapsulation in the treatment of vertebral compression fractures.	Identical
Implant Material	Polymethylmethacrylate	Polymethylmethacrylate	Identical

Element of Comparison	Vertaplex HV High Viscosity Radiopaque Bone Cement Subject Device	Vertaplex HV High Viscosity Radiopaque Bone Cement Predicate Device K192818	Comparison
Regulatory Information Comparison			
Classification	Class II	Class II	Identical
Regulation	21 CFR 888.3027	21 CFR 888.3027	Identical
Product Code	NDN, PML	NDN, PML	Identical
Panel	Orthopedic	Orthopedic	Identical
Intended Use and Indications for Use Comparison			
Intended Use	Fixation of vertebral compression fractures, restoration of integrity of spinal column (with ES2)	Fixation of vertebral compression fractures, restoration of integrity of spinal column (with ES2)	Identical
Indications for Use	Vertaplex® HV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma). When used in conjunction with ES2® Augmentable Spinal System, Vertaplex® High Viscosity (HV) Radiopaque Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Vertaplex® High Viscosity (HV) Radiopaque Bone Cement and the ES2® Augmentable Spinal System are for use together at spinal levels where the structural integrity of the spine is not severely compromised. When used in conjunction with SpineJack® Expansion Kit, Vertaplex® High Viscosity (HV) Radiopaque Bone Cement is also indicated for the fixation of	Vertaplex HV Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma). When used in conjunction with ES2® Augmentable Spinal System, Vertaplex® High Viscosity (HV) Radiopaque Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Vertaplex® High Viscosity (HV) Radiopaque Bone Cement and the ES2® Augmentable Spinal System are for use together at spinal levels where the structural integrity of the spine is not severely compromised.	Different Addition of indication for use with SpineJack for fixation of pathological or non-pathological traumatic vertebral compression fractures

	osteoporotic or traumatic AO/ Magerl Type A vertebral compression fractures.		
Contraindications	• Allergies or sensitivity to any of its chemical components • The presence of active or incompletely treated infection at the site where the bone cement is to be injected. • Coagulation disorders, or with severe cardiopulmonary disease • Spinal stenosis (>20% by retropulsed fragments) • Vertebral plana (collapse >90%) • Compromise of the vertebral body or the walls of the pedicles • For vertebroplasty, unstable vertebral fractures due to posterior involvement • Patient clearly improving on medical therapy • Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture • For vertebroplasty/sacroplasty, non-pathological acute traumatic fractures of the vertebra/sacrum • Displaced sacral fractures • Compromise of the sacral foramina • If sacral surgical fusion may be required	• Allergies or sensitivity to any of its chemical components • The presence of active or incompletely treated infection at the site where the bone cement is to be injected. • Coagulation disorders, or with severe cardiopulmonary disease • Spinal stenosis (>20% by retropulsed fragments) • Vertebral plana (collapse >90%) • Compromise of the vertebral body or the walls of the pedicles • Unstable vertebral fractures due to posterior involvement • Patient clearly improving on medical therapy • Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture • Non-pathological, acute traumatic fractures of the vertebra/sacrum • Displaced sacral fractures • Compromise of the sacral foramina • If surgical fusion may be required	Similar – Clarification that use of bone cement for sacroplasty or vertebroplasty (using cement alone) for treatment of non-pathological acute traumatic fractures or for unstable vertebral fractures due to posterior involvement are contraindicated Additionally, clarification is made to specify that use in sacral surgical fusion is contraindicated
Technological Comparison			
Contact	Implantable	Implantable	Identical
Principal of Operation	Powder and liquid components are mixed together so that they polymerize and form a hardened acrylic polymer. The mixture is in a pourable and injectable state for a period of time, before it cures to form a hardened structure, capable of long-term load support, bone augmentation and implant encapsulation in the treatment of vertebral compression fractures.	Powder and liquid components are mixed together so that they polymerize and form a hardened acrylic polymer. The mixture is in a pourable and injectable state for a period of time, before it cures to form a hardened structure, capable of long-term load support, bone augmentation and implant encapsulation in the treatment of vertebral compression fractures.	Identical
Implant Material	Polymethylmethacrylate	Polymethylmethacrylate	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 Real World Evidence (RWE) consisting of outside-of-US clinical data published in the clinical literature and a post-market outside-of-US clinical study. The SpineJack implant was previously tested to be non-pyrogenic.

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 of reduction/fixation of osteoporotic VCF are a subset of the intended use. Therefore, the subject devices have the same intended use as the predicates.

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 traumatic VCFs. The literature shows that the safety profile for SpineJack/cement for use in painful osteoporotic VCFs and for traumatic VCFs is nearly the same. No different types of adverse events are seen in trauma as compared to 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 the reduction of traumatic vertebral compression fractures. Therefore, a decision of substantial equivalence is supported.