August 31, 2020

DePuy Spine, Inc.
Sergio Cordeiro
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K201831
Trade/Device Name: CONFIDENCE® Spinal Cement System, VERTEBROPLASTIC™ Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN
Dated: July 1, 2020
Received: July 2, 2020

Dear Sergio Cordeiro:

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)*

K201831

Device Name

CONFIDENCE® Spinal Cement System

Indications for Use *(Describe)*

The CONFIDENCE SPINAL CEMENT SYSTEM® is intended for percutaneous delivery of the CONFIDENCE™ High Viscosity Spinal Cement, which is indicated for fixation of pathological fractures of the vertebral body during vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancer, myeloma).

When the CONFIDENCE™ High Viscosity Spinal Cement is used in conjunction with the VIPER® and EXPEDIUM® Fenestrated Screw Systems, the 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. The VIPER® and EXPEDIUM® Fenestrated Screw Systems augmented with the CONFIDENCE™ High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201831

Device Name
VERTEBROPLASTIC™ Radiopaque Bone Cement

Indications for Use *(Describe)*

The VERTEBROPLASTIC Radiopaque Bone Cement is indicated for the treatment, using vertebroplasty or kyphoplasty procedures, of pathological fractures of the vertebral body caused by osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

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

A. Submitter Information

Manufacturer:
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FY4 4QQ
United Kingdom

Submitter:
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USA

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Email: scordei1@its.jnj.com

B. Date Prepared

July 1, 2020

C. Device Name

Trade/Proprietary Names: CONFIDENCE® Spinal Cement System
VERTEBROPLASTIC™ Radiopaque Bone Cement

Common/Usual Names: Cement, Bone, Vertebroplasty

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement
Class II per 21 CFR §888.3027

Product Code: NDN

Review Panel: Orthopedic

D. Predicate Device Names

Primary Predicate:	CONFIDENCE® Spinal Cement System (K060300)
Additional Predicates:	VERTEBROPLASTIC™ Radiopaque Bone Cement (K071927)
	CONFIDENCE™ High Viscosity Spinal Cement, VIPER® and EXPEDIUM® Fenestrated Screw Systems (K160879)

E. Submission Purpose

Obtain clearance for magnetic resonance compatibility labeling of the systems listed.

F. Device Descriptions

CONFIDENCE® Spinal Cement System
The CONFIDENCE cement is a self-curing, polymethylmethacrylate (PMMA) radiopaque bone cement. Its package includes two sterile components: a sachet containing powder polymer and an ampoule containing liquid monometer.

VERTEBROPLASTIC™ Radiopaque Bone Cement
The VERTEBROPLASTIC Radiopaque Bone Cement is a self-curing methyl methacrylate cement consisting of a powder polymer component and a liquid monomer component. The powder component is contained within a foil pouch and the liquid component in a sterile ampoule within a blister pack. The blister pack and the foil pouch are held securely on a card insert that is sealed into a peelable pouch.

G. Intended Use

CONFIDENCE® Spinal Cement System
The CONFIDENCE SPINAL CEMENT SYSTEM® is intended for percutaneous delivery of the CONFIDENCE™ High Viscosity Spinal Cement, which is indicated for fixation of pathological fractures of the vertebral body during vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancer, myeloma).

When the CONFIDENCE™ High Viscosity Spinal Cement is used in conjunction with the VIPER® and EXPEDIUM® Fenestrated Screw Systems, the 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. The VIPER® and EXPEDIUM® Fenestrated Screw Systems augmented with the CONFIDENCE™ High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

VERTEBROPLASTIC™ Radiopaque Bone Cement
The VERTEBROPLASTIC Radiopaque Bone Cement is indicated for the treatment, using vertebroplasty or kyphoplasty procedures, of pathological fractures of the vertebral body caused by osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

H. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The subject devices maintain the design characteristics of the predicate devices. Intended use remains consistent with the predicate devices. The subject devices are provided with additional labeling language regarding magnetic resonance (MR) compatibility.

I. Materials

The subject device materials remain identical to the predicate device materials, which consist of a liquid and a powder. The liquid component is mainly composed of methyl methacrylate. The major powder components are polymethylmethacrylate (PMMA), hydroxyapatite and barium sulfate. Benzoyl peroxide which initiates the polymerization is included in the polymer powder.

J. Performance Data

Non-clinical evaluation was conducted in alignment with the following standards:

- ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

Results demonstrated compatibility conditions of the subject devices in the MR environment.

K. Conclusion

Evaluation of subject device intended use and technological characteristics demonstrates substantial equivalence with the predicate devices. Performance data supports the addition of magnetic resonance compatibility information to subject device labeling.