Safe Orthopaedics
Pierre Dumouchel
CEO
Parc des Bellevues, Le Californie - Allee Rosa Luxemburg
Eragny Sur Oise, 95610
France

July 30, 2020

Re: K201648
Trade/Device Name: Sterispine™ PS
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ
Dated: June 16, 2020
Received: June 18, 2020

Dear Pierre Dumouchel:

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

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal 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)*
K201648

Device Name
Sterispine™ PS

Indications for Use *(Describe)*
The Sterispine™ PS system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct of fusion. Sterispine™ PS system is intended for posterior non-cervical, pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e, fracture or dislocation) ; spinal stenosis ; tumor ; pseudoarthrosis and failed previous fusion.

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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Traditional 510k
STERISPINE™ PS

510(k) SUMMARY

510k	Traditional
Basis for submission	Extension of the product line
Submitted by	Safe Orthopaedics Parc des Bellevues Le Californie - Allée Rosa Luxemburg 95610 Eragny-sur-Oise, France
Contacts	Pierre DUMOUCHEL (CEO) Phone number 33 (0) 1 84 28 01 79 e-mail p.dumouchel@safeorthopaedics.com Regulatory contact: Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Date Prepared	July 23, 2020
Common Name	Pedicle screw spinal system
Trade Name	Sterispine™ PS
Classification Name	Thoracolumbosacral pedicle screw system
Class	II
Product Code	NKB, KWQ
CFR section	888.3070
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: Sterispine™ PS manufactured by SAFE ORTHOPAEDICS (K170528) Additional predicates: CD HORIZON™ Fenestrated Screw Set manufactured by Medtronic Sofamor Danek (K170347), Synergy 4.0 mm, 4.5 mm VLS screws manufactured by Interpore Cross Intl (K011437), Sterispine™ Ps manufactured by SAFE ORTHOPAEDICS (K151921, K151747, K150092, K140802, K130632, K121299, K112453)

Indications for use	The Sterispine™ PS system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct of fusion. Sterispine™ PS system is intended for posterior non-cervical, pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e, fracture or dislocation) ; spinal stenosis ; tumor ; pseudoarthrosis and failed previous fusion.
Description of the device	The cleared range of Sterispine™ PS system includes multiaxial screws and cannulated multiaxial screws with or without extended head (Ø5.5, 6.5 and 7.5mm, lengths from 25 to 85mm) and straight and prebent rods (Ø5.5, 6.5 and 7.5mm, lengths from 30 to 380mm). Sterispine™ PS implants are supplied sterile with a sterile single-use set of surgical instruments supplied in kits. Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.
Technological characteristics compared to the predicate devices	The present submission is an extension of the product line that includes - Modified and new sterile single-use surgical instruments - Add of a cross-connector kit - Add of multi-axial fenestrated screws (with and without extended head) - Add of Ø4.5 mm for all STERISPINE™ PS screws As established in this submission, the modified or added components are substantially equivalent to predicate devices in areas including indications for use, function materials in contact with patients and technological and mechanical characteristics. The safety and effectiveness of Sterispine™ PS fenestrated screws have not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.
Discussion of Testing	The following non-clinical tests were conducted on the STERISPINE™ PS system Mechanical testing of fenestrated screw ϕ4.5 mm / with cross -connector where applicable): - Axial Grip, Flexural Grip, Torsional Grip and Dynamic Flexion per ASTM F1798 - Static Compression Bending, Static Tension Bending, Static Torsion and Dynamic compression per ASTM F1717. Results demonstrate that the Sterispine™ PS system meets or exceeds functional requirements and suitability for use. Additionally, the Sterispine™ PS system performs equivalent or better than predicates systems. - Functional evaluation of the cross-connector and associated surgical instrumentation All tests met the acceptance criteria - Functional testing of the single-use surgical instruments

	Overall functional testing demonstrates that the new added surgical instruments can be assembled with each component of the Sterispine PS instrument/implant kit. No deterioration or blocking were observed during the functional testing. Additional mechanical and / or functional testings conducted on Jamshidi, threaded rod introducer, spatula, screw extender arm, fenestrated screwdriver, persuader and handle show that surgical instruments are suitable and fulfill requirements for single-use.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the added surgical implants and the added or modified sterile single-use surgical instruments have demonstrated substantial equivalence to the identified predicate devices.