DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 9, 2017

Safe Orthopaedics
Mr. Pierre Dumouchel
Chief Executive Officer
Parc des Bellevues, Allée Rosa Luxembourg – Batiment le Californie
95160 Eragny sur Oise
FRANCE

Re: K170528
Trade/Device Name: Sterispine™ PS
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: February 21, 2017
Received: February 22, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170528

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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510(k) Summary

510k	Special 510k
Basis for Submission	New devices
Submitted by	SAFE ORTHOPAEDICS Allée Rosa Luxembourg Parc des Bellevues- Batiment le Californie 95610 – Eragny sur Oise France
Contacts	Pierre DUMOUCHEL- CEO p.dumouchel@safeorthopaedics.com Regulatory contact: Isabelle DRUBAIX (Idée Consulting) idee-consulting@nordnet.fr
Date prepared	March 7th 2017
Common name	Pedicle screw spinal system
Trade Name	Sterispine™ PS
Classification name	Thoracolumbosacral Pedicle Screw System
Class	II
Product code	NKB
CFR section	888.3070
Device panel	Orthopedic
Legally marketed predicate devices	Primary predicate: Sterispine™ PS K112453, Additional predicates: Sterispine™ PS K121299, K130632, K140802, K151747, K151921)
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 include multiaxial screws and cannulated multiaxial screws with or without extended head (Ø5.5, 6.5 and 7.5mm, lengths from 25 to 60mm) and straight and prebent rods (Ø5.5, 6.5 and 7.5mm, lengths from 30 to 380mm). Components of Sterispine™ PS range of products is supplied sterile with a sterile single-use set of surgical instruments.

Technological characteristics	The screw lengths added within this submission for each screw diameter (Ø5.5, 6.5 and 7.5mm) is 65 to 85mm.
Discussion of testing	Sterispine™ PS conforms to special control established for pedicle screw spinal system and to Spinal system 510(k)s- Guidance for industry and FDA staff Document issued on May 3, 2004. The following testing were conducted on the Sterispine™ PS predicate device (K112453): Mechanical testing per ASTM F1717 standard test method for spinal implant constructs in a vertebrectomy model and ASTM F1798 standard guide for evaluating the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis implants. Testing according to ASTM F1717 includes static compression, static torsion and dynamic compression. Testing according to ASTM F1798 includes Static slipping, static bending and static rotation. Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device. These tests result have demonstrated comparable mechanical properties to predicates devices. It has been demonstrated that the added sizes of screws are not worst cases. So, the worst case screw that has been previously identified and tested (K112453, K151921). No additional risks have been identified when compared with Sterispine™ PS screws previously cleared. Consequently, no new additional testing was needed for the added sizes.
Conclusion	The extended range of Sterispine™ PS system is substantially equivalent to its predicate devices Sterispine™ PS (K112453, K121299, K130632, K140802, K151747, K151921) in terms of intended use, material, design, mechanical properties and function.