DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 21, 2015

Safe Orthopaedics
Mr. Pierre Dumouchel
QARA Director
Parc des Bellevues
Allée R. Luxembourg – Bat. Californie
95610 Eragny Sur Oise
France

Re: K151756
Trade/Device Name: STERISPINE™ LC Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 25, 2015
Received: June 29, 2015

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" (21CFR 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 yours,

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)*
K151756

Device Name
STERISPINE™ LC CAGE

Indications for Use *(Describe)*

The SteriSpine™LC device is indicated for intervertebral body fusion procedures at one or two contiguous levels from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. This device is to be used with autogenous bone graft to facilitate fusion and is intended for use with SteriSpine™ PS, a supplemental fixation system cleared by the FDA for use in the lumbar spine.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

510k	Traditional
Submitted by	Safe Orthopaedics Parc des Bellevues Allée R. Luxembourg - Le Californie 95610 Eragny sur Oise – FRANCE
Contacts	Pierre DUMOUCHEL Industrialization Director / QARA Director p.dumouchel@safeorthopaedics.com +33 (0) 1 34 21 50 00 Isabelle Drubaix Regulatory contact idee-consulting@nordnet.fr +33 (0)3 21 05 64 23
Date Prepared	June 3rd 2015
Common Name	Intervertebral body fusion device
Trade Name	STERISPINE™ LC CAGE
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Class	II
Product Code	MAX
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate device: STERISPINE™ LC CAGE manufactured by Safe Orthopaedics cleared under K133893 Additional predicate device: STERISPINE™ LC CAGE manufactured by Safe Orthopaedics cleared under K122021
Indications for use	The SteriSpine™LC device is indicated for intervertebral body fusion procedures at one or two contiguous levels from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. This device is to be used with autogenous bone graft to facilitate fusion and is intended for use with SteriSpine™ PS, a supplemental fixation system cleared by the FDA for use in the lumbar spine.

Description of the device	The SteriSpine™LC cages are intervertebral body fusion devices with a central cavity available either in straight rectangular shape for transforaminal (TLIF) or posterior (PLIF) approach and in curved shape for transforaminal (TLIF) approach. The SteriSpine™LC cages are made of PEEK (Zeniva ZA-500) conforming to ASTM F2026 with Tantalum markers conforming ASTM F560 to visualize the position of the implant in the disc space. The SteriSpine™LC cages are available in several sizes to adapt to anatomical variations. The SteriSpine™LC range of products is supplied sterile with a sterile single-use set of surgical instruments.
Technological Characteristics	There have been no changes made to the SteriSpine™LC implants (K122021 and K133893). The purpose of this 510(k) submission is to obtain clearance for added bifunctional instruments to the SteriSpine™LC sterile single-use set of surgical instruments, and for a redesigned quick change handle. Additionally, sulfate barium has been added in the raw material of the dual trial and the dual spreader in order to improve visibility. Finally, a "window" has been added to the external packaging of SteriSpine™LC devices supplied sterile. This new packaging will be used for all devices manufactured by Safe Orthopaedics.
Discussion of Testing	The following non-clinical tests were conducted: biocompatibility testing according to ISO 10993-5, ISO 10993-10 and ISO 10993-11 for the new or modified raw materials; packaging validation according to ISO 11607-1 and 11607-2 and sterilization revalidation according to ISO 11137-1, 11137-2 and 11137-3. Results demonstrate that the performance of the subject device system is substantially equivalent to the cited predicates.
Conclusion	Non clinical performance testing demonstrates that the added or modified surgical instruments are substantially equivalent to predicate devices in terms of intended use, materials, design and function.