SEP 20 2012

# 510(k) SUMMARY

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| Submitter | Safe Orthopaedics<br>Parc des Bellevues<br>Allée R. Luxembourg - Le Californie<br>95610 Eragny sur Oise – France |
| Contacts | Regulatory contact Isabelle Drubaix<br>idee-consulting@nordnet.fr<br>+33 (0)3 21 05 64 23<br>QARA Director : Pierre DUMOUCHEL<br>p.dumouchel@safeorthopaedics.com<br>+33 (0) 1 34 21 50 00 |
| Trade Name | SteriSpine™LC |
| Classification Name | Intervertebral body fusion device |
| Class | II |
| Product Code | MAX |
| CFR section | 888.3080 |
| Device panel | Orthopedic |
| Legally marketed predicate devices | Lumbar I/F cage (P960025) manufactured by Depuy Acromed<br>Zavation IBF System (K112664) manufactured by Zavation LLC |
| Description | SteriSpine™LC range of products consists of lumbar Interbody fusion devices available in sizes to adapt to anatomical variations. SteriSpine™LC is dedicated to transforaminal approach and is manufactured as single solid-machined piece made of PEEK conforming ASTM F2026. Markers made of tantalum conforming to ASTM F560-08 are used to visualize the position of the implant in the disc space. STERISPINE LC Lumbar Interbody Devices are supplied sterile with a single-use set of surgical instruments. |
| Indications for use | 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.<br>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 |
| Performance data | SteriSpine™LC Lumbar Interbody Device conforms to Class II Special Controls Guidance Document: Intervertebral Body Fusion Device- Document issued on: June 12, 2007.<br>Mechanical testing includes shearing, compression and torsion performed according to ASTM F2077-03, subsidence testing performed according to ASTM F2267-04 and expulsion testing.<br>Results demonstrate comparable mechanical properties to the predicate device. Cadaver testing performed to validate the instrumentation have been presented. No clinical data has been presented. |
| Substantial equivalence | SteriSpine™LC is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function. Non clinical performance testing according to special control demonstrate that SteriSpine™LC is as safe, as effective, and performs as safely and effectively as its predicate devices. |
| Date | 2012July06 |

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

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

Re: K122021
Trade/Device Name: STERISPINE LC Lumbar Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 6, 2012
Received: July 10, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

**510(k) Number (if known):** K122021

**Device Name:** STERISPINE LC Lumbar Interbody Device

**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

| Prescription Use ✓ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122021