JUL 16 2010

510(k) SUMMARY

As required by section 807.92

Submitter	SPINEART International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 799 40 25 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.ch Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Preparation date	June 16, 2010
Trade Name	JULIET® OL Intervertebral body fusion device
Classification Name	Intervertebral body fusion device
Class	II
Product Code	MAX
CFR section	21 CFR 888.3080
Device panel	Orthopedic
Legally marketed predicate devices	DYNAMIK INTERVERTEBRAL BODY FUSION DEVICE (K081888) manufactured by SPINEART.
SPECIAL 510k	JULIET OL - Extension of range of products
Description	JULIET® range of products consists of lumbar Interbody cages available in various models to adapt to anatomical variations and surgical techniques. JULIET® OL cages are dedicated to transforaminal approach and are manufactured as single solid-machined piece made of PEEK conforming ASTM F2026. Markers made of tantalum conforming to ASTM F0560 are used to visualize the position of the implant in the disc space. JULIET® OL Lumbar Interbody Devices are supplied either sterile or non sterile with a complete set of surgical instruments.

Intended Use	JULIET® Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1, DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft. JULIET® Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Performance data	JULIET® OL Lumbar Interbody Device conforms to Class II Special Controls Guidance Document: Intervertebral Body Fusion Device- Document issued on: June 12, 2007. Mechanical testing includes static axial compression performed according to ASTM F2077-03 and subsidence testing performed according to ASTM F2267-04. Results demonstrate that additional components perform as safely and effectively as their predicate devices.
Substantial equivalence	JULIET® OL Lumbar Interbody Device 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 additional components are as safe, as effective, and performs as safely and effectively as their predicate devices.

Revised July 16, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUL 16 2010

SPINEART
% Mr. Franck Pennesi
Director of Industry and Quality
International Center Cointrin
20 route de pre-bois, CP1813
1215 Geneva 15 Switzerland

Re: K101720
Trade/Device Name: JULIET® OL Lumbar Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 16, 2010
Received: June 18, 2010

Dear Mr. Pennesi:

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.

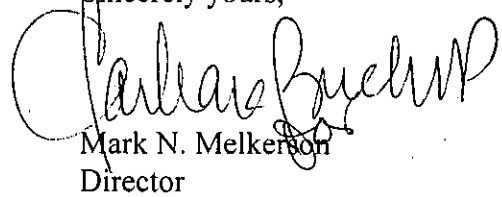
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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): K101720

Device Name: JULIET® OL Lumbar Interbody Device

Indications For Use:

JULIET® OL Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolistesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. JULIET® OL Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K101720