K081165

DEC 17 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

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
Trade Name	ELLIPSE Lumbar posterior osteosynthesis system
Common Name Classification Name	Pedicle screw spinal system
Device classification	21 CFR 888.3070
Product code	MNI, MNH, KWP
Legally marketed predicate devices	SYNERGY (K011437) and XIA Spinal system (numerous 510k including K013823)
Description	ELLIPSE posterior osteosynthesis system includes pedicular screws, spondylolistesis screws longitudinal rods and transverse connector rods, connector and nut. All components of ELLIPSE posterior osteosynthesis system are made of TA6V4ELI conforming to ISO 5832.3 and ASTM F 136. ELLIPSE components are supplied either sterile or not sterile and with a complete set of surgical instruments.
Intended Use	ELLIPSE Lumbar posterior osteosynthesis system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).
Performance data	ELLIPSE Lumbar posterior osteosynthesis system 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. Mechanical testing was conducted per ASTM 1717
Substantial equivalence	ELLIPSE Lumbar posterior osteosynthesis system is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties according to ASTM 1717 and function.

Revised December 16, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spineart
% Mr. Franck Pennesi
Director of Industry and Quality
International Center
Cointrin 20 Route de Pre-Bois
CP1813
Geneva, Switzerland 1215

DEC 17 2008

Re: K081165
Trade/Device Name: ELLIPSE posterior osteosynthesis system
Regulation Number: 21 CFR 888.2070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: December 8, 2008
Received: December 10, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K081165

Device Name: ELLIPSE posterior osteosynthesis system

Indications for Use:

ELLIPSE posterior osteosynthesis system is intended to use in the non cervical spine. When use as a pedicle screw fixation system, ELLIPSE is intended for patients: a) having severe spondylolisthesis (grades 3 and 4) at the fifth lumbar – first sacral (L5-S1) vertebral joint; b) who are receiving fusions using autogenous bone graft only; c) who are having the device fixed or attached to the lumbar and sacral spine and d) who are having the device removed after the development of a solid fusion mass.

When use as a pedicle screw fixation system, ELLIPSE is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1- S1): degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081165

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