K062570 1/2

KLS martin L.P.

510(K) SUMMARY

OCT 3 1 2006

Submitter: KLS-Martin, L.P.
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Contact Person: Jennifer Damato
Director RA/QA

K-36

FDA/CDRH/ODE/RHO
2006 AUG 31 A 11:58

Date of Summary: 18 August 2006

Device Name: Patient Contoured Mesh (PCM)

Trade Name: PCM

Common Name: Titanium Panel

Classification Name and Number: Plate, Cranioplasty, Preformed, Non-Alterable (CFR 882.5330)

Regulatory Class: II

Predicate Devices: Stryker Custom TI Implant (K052871)

Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199)

Synthes (USA) Patient Specific Cranial/Craniofacial Implant (K033868)

KLS-Martin Micro Osteosynthesis System (1.5 mm) (K944565)

Centre-Drive Drill Free Screws (DFS) (K971297)

Intended Use: Patient Contoured Mesh (PCM) is intended to replace bony voids in mandibular, maxillofacial or craniofacial skeleton.

Device Description: Patient Contoured Mesh (PCM) is a custom shaped titanium panel that is pre-shaped to fit the anatomy of the patient using a CT based model of the patient. Patient Contoured Mesh

(PCM) is fixated using standard KLS Martin's 1.5mm titanium screws (K971297)

Technological Characteristics:

Similarities to Predicate

Patient Contoured Mesh (PCM) and Stryker Custom TI Implant (K052871), Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199) and Synthes (USA) Patient Specific Cranial/Craniofacial Implant (K033868) are patient specific implants that are manufactured from titanium.

Patient Contoured Mesh and KLS-Martin Micro Osteosynthesis System (1.5 mm) (K944565) are identical in materials and in the intended use for reconstructive procedures of the mandibular, maxillofacial or craniofacial skeleton.

Differences to Predicate

Patient Contoured Mesh (PCM) is manufactured from CP Titanium and Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199) and Synthes (USA) Patient Specific Cranial/Craniofacial Implant (K033868) are manufactured from titanium and PEEK

Substantial Equivalence:

Patient Contoured Mesh (PCM) is substantially equivalent in materials and patient specificity to the Stryker Custom TI Implant (K052871), Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199) and Synthes (USA) Patient Specific Cranial/Craniofacial Implant (K033868)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

KLS-Martin L.P.
% Ms. Jennifer Damato
Director RA/QA
11239 St. Johns Industrial Parkway South
Jacksonville, Florida 32246

OCT 3 1 2006

Re: K062570
Trade/Device Name: Patient Contoured Mesh
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: August 18, 2006
Received: August 31, 2006

Dear Ms. Damato:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its 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

1/1

Indications for Use

K062570

510(k) Number (if known):

Device Name: Patient Contoured Mesh (PCM)

Indications For Use:

Patient Contoured Mesh (PCM) is intended to replace bony voids in mandibular, maxillofacial or craniofacial skeleton.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 General, Resto
and Neurological Devices

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