DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 9, 2015

KLS Martin L.P.
Ms. Jennifer Damato
Director of Quality MGT & Regulatory Affairs
P.O. Box 16369
Jacksonville, Florida 32245-6369

Re: K151382
Trade/Device Name: Patient Contoured Implant - PEEK (PCI-PEEK)
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: October 7, 2015
Received: October 8, 2015

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. 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" (21 CFR 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K151382

Device Name
Patient Contoured Implant - PEEK (PCI-PEEK)

Indications for Use *(Describe)*
The Patient Contoured Implant - PEEK (PCI-PEEK) is intended to replace bony voids in the cranial skeleton.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary
Section 21 CFR 807.92

Submitter:	KLS-MARTIN L.P. 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Jennifer Damato Director of Quality MGT & Regulatory Affairs Phone: 800-625-1557 Fax: 904-641-7378
Date Prepared:	November 4, 2015
Trade Name:	Patient Contoured Implant – PEEK (PCI-PEEK)
Common Name:	Preformed Plate
Classification:	Plate, Cranioplasty, Preformed, Non-alterable Class II, 21 CFR 882.5330, Product Code GXN
Predicate Devices:	Patient Contoured Mesh – PEEK (PCM-P) **[K072707]** **No reference devices were used in this submission.**

Device Description:
The Patient Contoured Implant – PEEK (PCI-PEEK) is a preformed implant manufactured from PEEK material. The implant is pre-shaped to fit the anatomy of the patient using a CT-based model of the patient's skull. The PCI-PEEK is fixated to native bone using previously cleared KLS Martin titanium plates and screws.

The purpose of this premarket notification is to offer the implants sterile.

Indications for Use:
The Patient Contoured Implant – PEEK (PCI-PEEK) is intended to replace bony voids in the cranial skeleton.

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Technological Characteristics / Substantial Equivalence:

	Patient Contoured Implant – PEEK (PCI-PEEK) (Subject Device)	**Patient Contoured Mesh – PEEK (PCM-P) (Predicate: K072707)**
Indications for Use	The Patient Contoured Implant – PEEK (PCI-PEEK) is intended to replace bony voids in the cranial skeleton.	Patient Contoured Mesh – PEEK (PCM-P) is intended to replace bony voids in the cranial and/or craniofacial skeleton.
Anatomical Sites	Cranial	Craniomaxillofacial
Material	PEEK	PEEK
Style	Solid or solid with holes	Solid or solid with holes
Sterilization	Provided Sterile (Gamma)	Provided Non-sterile (Steam)
Method of Fixation	Titanium Screws and Titanium Plates	Titanium Screws and Titanium Plates
Where used (hospital, home, ambulance, etc)	Health Care Facilities / Hospitals	Health Care Facilities / Hospitals

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Performance Data:

Biocompatibility Testing

The biocompatibility evaluation for the Patient Contoured Implant – PEEK (PCI-PEEK) was conducted in accordance with the FDA Blue Book Memorandum #G95-1, "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process,' as recognized by FDA.

The patient-contacting material PEEK (Polyether ether ketone) used for the Patient Contoured Implant – PEEK (PCI-PEEK) is previously cleared in K072707. The implant has identical chemical composition, undergoes identical manufacturing processes, and has the same permanent body contact duration as the predicate, K072707.

LAL endotoxin testing demonstrates that the sterile PEEK implant conforms to the required < 2.15 EU/device endotoxin lot release specification.

Clinical Studies

Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence Conclusion:

The subject device, Patient Contoured Implant – PEEK (PCI-PEEK), has the same intended use, design, function, and is composed of the same material as the predicate, Patient Contoured Mesh – PEEK (PCM-P). The subject device differs from the predicate in that it will be offered in sterile packaging. The similarities in technological characteristics do not raise new issues of safety or effectiveness and demonstrate substantial equivalence to the predicate device.