K103582

KELYNIAM GLOBAL, INC.
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510(k) Summary
Kelyniam Custom Skull Implant

APR 1 4 2011

510(k) Submitter Kelyniam Global, Inc.
200 Myrtle Street, 2nd Floor
New Britain, CT 06053
(800) 280-8192

Contact Person: James Ketner President/CEO
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(860) 832-9331, Ext 223
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Date of Summary: 25 October 2010

Device Name: Proprietary Name: Kelyniam Custom Skull Implant (CSI)
Common Name: Patient-specific cranial implant
Classification Name: "plate, cranioplasty, preformed, non-alterable,' a class II device in accordance with 21 CRF §882.5330

Panel: Neurology

Product Code: GXN

Device Description:

The Kelyniam Custom Skull Implant (CSI) is designed individually for each patient to correct defects in cranial bone. The Kelyniam Custom Skull Implant (CSI) is individually sized and shaped implantable prosthetic cranioplasty plates intended to fill defects in a specific patient's cranial skeleton. The implants are composed of PEEK-OPTIMA, and are fabricated using the patient's CT imaging data. The implants are provided with .125" diameter pressure relief holes, equally spaced over the contour of the implant with .625" centerline spacing and a minimum of .500" edge margin. The devices are provided non-sterile for sterilization prior to implantation and are attached to the native bone with commercially available cranioplasty fasteners. This product is a single use device.

Indications for use:

The Kelyniam Custom Skull Patient Specific Cranial implant is intended to replace bony voids in the cranial skeleton.

Toxicity

A series of Limulus Amebocyte Lysate (LAL) test were performed. In these test, the Kelyniam Custom Skull Implants detected endotoxin levels were lower than the minimum requirements for medical devices in contact with cerebrospinal fluid.

Substantial Equivalence:

The Kelyniam Custom Skull Implants (CSI) are substantially equivalent to the Synthes Patient Specific Cranial Implant (PSCI) (K053199), OsteoSymbionics Patient-Specific Cranial Implant (K072601) and KLS Martin Patient Contoured Mesh (K072707). Like these other devices, the Kelyniam Custom Skull Implant (CSI) is manufactured from PEEK or equivalent polymers, sold non-sterile and is customized to each patient.

Substantial Equivalence Chart

	Kelyniam Custom Skull Implant (CSI)	Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199)	OsteoSymbionics Patient-Specific Cranial Implant (K072601)	KLS Martin Patient Contoured Mesh (K072707)
Intended Use	Correction of defects in cranial bone	Replace bony voids in the cranial/craniofacial skeleton	Correct defects in craniofacial bone	Replace bony voids in the cranial and/or craniofacial skeleton
Material	PEEK-OPTIMA LT1	PEEK Optima-LT1	Polymethyl Methacrylate (PMMA)	PEEK (PCM-P)
Technical Specifications	Plate - Custom sized to each patient using CT data	Custom sized to each patient	Plate - Custom sized to each patient	Mesh - Custom sized to each patient
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. James Ketner
President/CEO/Chairman
Kelyniam Global, Inc.
200 Myrtle Street, 2nd Floor
New Britain, CT 06053

APR 14 2011

Re: K103582
Trade Name: Kelyniam Custom Skull Implant (CSI)
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: II
Product Code: GXN
Dated: October 25, 2010
Received: January 25, 2011

Dear Mr. Ketner:

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,

Keoia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K103582

Device Name: Kelyniam Custom Skull Implant (CSI)

Indications for Use: Patient Specific Cranial implants are intended for the replacement of bony voids in the cranial skeleton.

Prescription Use Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (21 CFR 801 Subpart C)

(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 Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K103582