KELYNIAM

K121755
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510(k) Summary

Kelyniam Customized Craniofacial Implant (CCI)

SEP 25 2012

510(k) Submitter/ Owner	Kelyniam Global, Inc. 97 River Road Canton, Connecticut 06019 Office (800) 280-8192
Contact Person:	Nicholas Breault Vice President of Production Office (800) 280-8192 Ext. 702 Cell (818) 269-9979 Fax (501) 641-2000
Date of Summary:	May 5, 2012
Device Name:	Proprietary Name: Kelyniam Customized Craniofacial Implant (CCI) Common Name: Patient Specific Plate Classification Name: "plate, cranioplasty, preformed, non-alterable,' a class II device in accordance with 21 CRF §882.5330
Panel:	Neurology
Product Code:	GXN

Indications for Use:

The Kelyniam Customized Craniofacial Implant (CCI) is intended to correct bony voids in the Craniofacial skeleton.

Device Description:

The implant is composed of Invibio Polyether Ether Ketone (PEEK-OPTIMA®) and fabricated using the patient's computed tomography (CT) imaging data. The device is provided non-sterile for steam sterilization prior to implantation and is attached to the native bone with commercially available FDA approved cranioplasty fixation systems. The Kelyniam Customized Craniofacial Implant (CCI) is a single use, non-load bearing device which is not intended to support any endosseous dental implants nor be used in areas where their intended use may be compromised in a subsequent surgery in the oral-maxillofacial area.

The implants will range in size from 50mm X 50mm to 150mm X 150mm, and the thickness of the implant ranging from 2mm – 4mm with the nominal thickness of 3mm. The sizes and shapes of this implant may vary depending on the patients specific defect area. The implant will attach to native bone using commercially-available cranioplasty fasteners.

The Customized Craniofacial Implant (CCI) is used to correct bony voids of the craniofacial region to include the zygoma, orbital rim, and adjacent bone. The Customized Craniofacial Implant (CCI) will not be used on any of the Maxilla bones that will affect the placement of current or future oral-maxillofacial implants, including endosseous dental implants. Also, the CCI Implant is not for use in the skeletal structures in the maxillofacial and/or oral regions.

Substantial Equivalence Chart

	Proposed Device	**Predicate 1**	**Predicate 2**	**Predicate 3**	**Predicate 4**
Device Name	Kelyniam Customized Craniofacial Implant (CCI)	Kelyniam Customized Skull Implant (CSI)	Synthes Patient Specific Cranial/Craniofacial Implant (PSCI)	KLS Martin Patient Contoured Mesh-PEEK (PCM-P)	MedCAD Accuhape™ PEEK Patient Specific Cranial Implant (PSCI)
510(k) number		K103582	K053199	K072707	K110684
Intended use	Correct bony voids in the Craniofacial skeleton	Correction of defects in cranial bone	Replace bony voids in the cranial/craniofacial skeleton	Replace bony voids in the cranial and/or craniofacial skeleton	Correct defects / replace bony voids in the cranial skeleton.
Material	PEEK-OPTIMA LT1	PEEK-OPTIMA LT1	PEEK Optima-LT1	PEEK	PEEK
Size (Length / Width)	($50mm^2$ – $150mm^2$)	(Max - $152mm^2$)	($100mm^2$ – $350mm^2$)	N/A	($10mm^2$ – $200mm^2$)
Thickness	2mm – 4mm	4mm	3mm	N/A	2mm – 4mm
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-Sterile
Sterilization Method	Steam	Steam	Steam	Steam	Steam

Substantial Equivalence Summary:

The Kelyniam Customized Craniofacial Implant (CCI) is substantially similar to predicate devices currently on the market. These devices include the Kelyniam Customized Skull Implant (CSI) (K103582), the Synthes Patient Specific Craniofacial Implant (PSCI) (K053199), the KLS Martin L.P. Patient Contoured Mesh – PEEK (PCM-P) (K072707) and the MedCAD AccuShape PEEK Patient Specific Cranial Implant (PSCI) (K110684). For a complete list please reference the table above.

Similar to these other devices the Kelyniam Customized Craniofacial Implant (CCI) implant is manufactured from INVIBIO™ PEEK-OPTIMA LT-1, sold non-sterile and customized to each individual patient's specific CT data. The recommended sterilization method for this device and the predicate devices is steam sterilization.

The Customized Craniofacial Implant (CCI) is used to correct bony voids of the craniofacial region to include the zygoma, orbital rim, and adjacent bone this differs from the Kelyniam Customized Skull Implant (CSI) and the MedCAD Accuhape™ PEEK Patient Specific Cranial Implant (PSCI) that are only used to correct bony voids in the Cranial skeleton.

Therefore, this supports the conclusion that the subject device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 25 2012

Kelyniam Global, Inc.
c/o Nicholas Breault
Vice President of Production
97 River Road, Suite A
Canton, Connecticut 06019

Re: K121755
Trade/Device Name: Kelyniam Customized Craniofacial Implant (CCI)
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed non-alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: August 31, 2012
Received: August 31, 2012

Dear Mr. Breault:

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,

Tesia 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

510(K) Number (If Known): K121755

Device Name: Kelyniam Customized Craniofacial Implant (CCI)

Indications For Use: The Kelyniam Customized Craniofacial Implant (CCI) is intended to correct bony voids in the Craniofacial skeleton

Prescription Use: **YES** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: **NO** (Part 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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121755