SDEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 19, 2017

OSSDSIGN AB
% David Weissburg
Principal
Weissburg Associates
808 Williamson Street, Suite 402
Madison, Wisconsin 53703

Re: K161090
Trade/Device Name: OSSDSIGN Cranial PSI
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PJN
Dated: December 13, 2016
Received: December 14, 2016

Dear Mr. Weissburg:

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,

Michael J. Hoffmann -S

for 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)*
K161090

Device Name
OSSDSIGN Cranial PSI

Indications for Use *(Describe)*
OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

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.

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510(k) SUMMARY

K161090

1. 510(k) Owner Name and Address:
   OSSDSIGN AB
   Virdings Alle 2,
   SE 754 50, Uppsala
   Sweden
   Telephone: +46 (0) 18-55 39 93
   Email: ub@ossdsign.com
   Contact: Ulrik Birgersson

2. Contact Person:
   David Weissburg
   Weissburg Associates
   808 Williamson St., Suite 402
   Madison, Wisconsin, 53703 USA

3. Date prepared: January 18, 2017

4. Trade Name: OSSDSIGN Cranial PSI

5. Regulation Description: Preformed Non-alterable Cranioplasty Plate

6. Classification Name: Plate, Preformed Non-alterable Cranioplasty Plate (21 CFR 882.5330, Product code: PJN)

7. Class: 2

8. Substantially equivalent to: KLS Martin – Patient Contoured Mesh (K062570)

9. Device Description: OSSDSIGN Cranial PSI (Patient Specific Implant) is a device that replaces native bone in the cranial skeleton. Each Cranial PSI is a patient-specific device specifically created for a patient's unique anatomical requirements. Cranial PSI consists of a rigid titanium mesh that is largely covered by biocompatible ceramic tiles. The ceramic tiles are in a mosaic pattern that provides space between tiles to allow free circulation of fluids.

10. Indications for Use: OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

11. Comparison of Technological Characteristics with the Predicate Device :

	OSSDSIGN Cranial PSI (K161090, subject device)	KLS Martin Patient Contoured Mesh (K062570, predicate)
Indications For Use	OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.	Patient Contoured Mesh (PCM) is intended to replace bony voids in mandibular, maxillofacial or craniofacial skeleton.
Materials	Ti grade 23, proprietary calcium phosphate ceramic	CP Titanium

	OSSDSIGN Cranial PSI (K161090, subject device)	KLS Martin Patient Contoured Mesh (K062570, predicate)
Titanium thickness	0.4 – 1.6 mm	0.6 – 1.0 mm
Max size	200 cm^2	200 cm^2
Provided form	Titanium and Ceramic Ceramic mixed and cured in manufacturer's facility	Titanium only
Sterility on delivery	Sterile	Non-sterile

12. Testing vs. predicate:

Test Method and Relevance Summary	Results	
	OSSDSIGN Cranial PSI	KLS Martin - PCI Titanium Mesh (K062570)
	Size: 197 cm^2	Size: 197 cm2
Dynamical Load Test: To verify that the Cranial PSI supports the forces exerted onto the implant from sleeping during the device lifetime. Requirement: no deformation Method: orbital shaker, 125 rpm, 60 hours. Relevance: test simulates changed head position every 20 minutes during 8 hours sleep for 50 years. Both the subject device and predicate passed the test.	No deformation	No deformation
Max Force [N] To establish the maximum force that can be applied to the device before failure. Requirement: >100 N Method: Universal testing machine at 1 mm/min Relevance: protection from falling objects and blunt trauma. Both the subject device and predicate passed the test. The subject device provided moderately better performance than the predicate.	461	383
Energy absorption [mJ] To establish the maximum energy the device can absorb before failure. Requirement: >1000 mJ Method: Universal testing machine at 1 mm/min Relevance: protection from falling objects and blunt trauma. Both the subject device and	2260	3760

predicate passed the test.		
Resistance to Deformation [mm] To establish device resistance to deformation before device failure. Requirement: <6 mm Method: Universal testing machine at 1 mm/min to 100 N applied force Relevance: Both the subject device and predicate passed the test.	0.5 mm	1.1 mm

13. Biocompatibility:

Test	Test Method Summary	Results
Cytotoxicity	ISO 10993-5 Method:L-929 mouse fibroblast cells	Not cytotoxic No evidence of causing cell lysis or toxicity
Sensitization	ISO 10993-10 Method: guinea pig maximization test	Non-sensitizer All test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
Sensitivity, Irritation	ISO 10993-6 Method: polar and non-polar test article extracts intracutaneously injected into five separate sites on the right side of the back of three rabbits. Observations for erythema and edema were conducted at 24, 48, and 72 hours.	Non-irritant Difference between the test and the control mean scores <1.0, confirming the device is a non-irritant
Systemic (acute) toxicity	ISO 10993-11 Method: 20 mice observed at 4, 24, 48 and 72 hours.	Non-toxic No mortality or evidence of systemic toxicity
Genotoxicity	ISO 10993-3 Method: mouse lymphoma forward gene mutation assay.	Not mutagenic <2-fold increase in mean mutant frequency of the L5178Y/TK cell line.
Mutagenicity	ISO-10993-3 Method: bacterial reverse mutation study	Non-mutagenic <2-fold increase in mutagenic frequency.
Implantation	ISO 10993-6 Test for local effects after implantation, 2- and 6-week subcutaneous implantations in rabbits.	Non-irritant Non-irritant compared to control.

Analytical Extractable Chemical Analysis	ISO 10993-12 Analysis by GC-MS, ICP-MS, LC-MS and HPLC-ELSD	Non-hazardous in all results, including extractions in polar, non-polar and mid-polar solvents. No hazardous materials detected.
Indirect Hemolysis	ISO 10993-4 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	The hemolytic index for the test article extract was 3.8% and the test article extract was slightly hemolytic. All samples passed the acceptance criteria.
Material Mediated Pyrogenicity	ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, Pyrogen Test	The total rise of temperatures during the 3 hour observation period was within acceptable limits. The test article was judged as nonpyrogenic. All samples passed the acceptance criteria

14. Conclusions:

Nonclinical tests demonstrate that Cranial PSI is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified in this summary.

- Cranial PSI mechanical performance in a battery of life-style emulating test scenarios shows substantial equivalence in mechanical effectiveness compared to the predicate device
- Cranial PSI demonstrated biocompatibility per current consensus standards