October 10, 2019

OSSDSIGN AB
% David Weissburg
Principal
Weissburg Associates
300 2nd Avenue SE, #14
St. Petersburg, Florida 33701

Re: K190523
Trade/Device Name: OSSDSIGN Cranial PSI Accessories
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PJN
Dated: September 9, 2019
Received: September 10, 2019

Dear David 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Matthew Krueger
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190523

Device Name
OSSDSIGN Cranial PSI Accessories

Indications for Use *(Describe)*
Cranial PSI Accessories are indicated for use as accessories to the OSSDSIGN Cranial PSI for the reconstruction of cranial defects. They are 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.

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

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510(k) SUMMARY

K190523

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
   300 2ND Avenue SE, Suite 14
   St. Petersburg, FL 33701 USA

3. Date prepared: October 10, 2019

4. Trade Name: OSSDSIGN Cranial PSI Accessories

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: OSSDSIGN Cranial PSI (Parent Device, K161090)

9. Device Description: OSSDSIGN Cranial PSI Accessories are optional devices that support physician use of the OSSDSIGN Cranial PSI (K161090) parent device. They are additively manufactured from PA2200 polyamide material. Each Cranial PSI Accessory is patient-specific and corresponds to a patient's unique anatomical requirements. Cranial PSI Accessories are intended to support implantation of the corresponding Cranial PSI parent device; both devices are designed from the same patient-specific computed tomography image data set.

   - Anatomical Model Original supports OSSDSIGN Cranial PSI by facilitating visual and tactile orientation for the physician of the patient's anatomy. It is provided non-sterile, is not intended to be sterilized and is not to be brought into contact with Cranial PSI, Plastic Drawing Guide or the Cranial Implant Trial.

   - Anatomical Model Modified supports OSSDSIGN Cranial PSI by facilitating visual and tactile orientation for the physician after removal of physician-specified regions. It is provided non-sterile, is not intended to be sterilized and is not to be brought into contact with Cranial PSI, Plastic Drawing Guide or the Cranial Implant Trial.

   - Plastic Drawing Guide supports accurate placement and fitting of OSSDSIGN Cranial PSI by assisting physicians in marking of bone intended for removal. Provided sterile.

   - Cranial Implant Trial supports placement and fitting of OSSDSIGN Cranial PSI by assisting physicians in confirming OSSDSIGN Cranial PSI fit, fixation point positions and soft tissue coverage. Provided sterile.

10. Indications for Use:
    Cranial PSI Accessories are indicated for use as accessories to the OSSDSIGN Cranial PSI for the reconstruction of cranial defects. They are 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 Accessories (subject device)	OSSDSIGN Cranial PSI (K161090) without Cranial PSI Accessories
Indications For Use	Cranial PSI Accessories are indicated for use as accessories to the OSSDSIGN Cranial PSI for the reconstruction of cranial defects. They are 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.	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.
Materials	PA2200	Ti grade 23, proprietary calcium phosphate ceramic
Max size	200 cm^2	200 cm^2
Provided form	Formed PA2200	Titanium and Ceramic Ceramic mixed and cured in manufacturer's facility
Sterility	Anatomical Model Original: provided non-sterile Anatomical Model Modified: provided non-sterile Plastic Drawing Guide: provided sterile Cranial Implant Trial: provided sterile	Cranial PSI: provided sterile

12. Biocompatibility of Cranial PSI Accessories:

Test	Test Method Summary	Results
Cytotoxicity	ISO 10993-5 Method:L-929 mouse fibroblast cells	Not cytotoxic. The test article extract showed no cytotoxic potential to L-929 mouse fibroblast cells.
Systemic (acute) toxicity	ISO 10993-11 Method: 20 mice observed at 4, 24, 48 and 72 hours	No systemic toxicity. There was no mortality or evidence of systemic toxicity from the extracts injected into mice.
Sensitization Study	ISO 10993-10 Method: Guinea Pig Maximization scored at 24 and 48 hours	Not a sensitizer. No evidence of delayed dermal contact sensitization.
Irritation Study	ISO 10993-10 Method: Intracutaneous study in rabbits scored at 24, 48 and 72 hours	Not an irritant. No evidence of irritation.
Pyrogen Study	USP 40-NF 35 Method: IV injection in 3 rabbits	Non-pyrogenic. No rabbit showed a temperature rise >0.5°C.
Hemolysis Study	ISO 10993-4 Method: human blood	Non-hemolytic. The mean hemolytic index for the test article extract was of 0.1%.
Analytical Extractable Chemical Analysis	ISO 10993-18 Method: extracts analyzed by FTIR, GC-MS, UPLC-MS, ICP-MS and GC-MS	Non-hazardous in all results. No leachables were detected in potentially toxic concentrations from a worst-case device configuration.

13. Performance Testing:

Test Method and Relevance Summary	Results
Deformation Test: Resistance to deformation simulating a clinician pressing hard with a surgical marker against the Plastic Drawing Guide. Requirement: <1mm deviation Method: test article supporting 200g weight	<1mm deformation in all cases
Simulated Clinical Use Study: Plastic Drawing Guide (PDG) evaluated for worst case friction and generation of particles. Requirement: no visible particles generated during the test or clinically acceptable particles. Method: 10X 360° screw rotations and 2 cm drop test, 10X magnification and visual inspection Relevance: there is slight friction associated with placement and removal of PDG into its corresponding anatomical location. This study simulates normal placement with a 5X worst-case bias.	No visible particles generated during the test.
Dimensional Integrity Test: Verification of dimensional integrity and fit. Requirement: no dimensional changes to any devices. Method: qualitative evaluation of fit after transport. Relevance: conforming manufacturing controls and packaging and shipping system.	No dimensional changes to any devices.

14. Conclusions: Nonclinical tests demonstrate that the Cranial PSI Accessories which are intended to be used with the Cranial PSI are substantially equivalent to the Cranial PSI.
    - Cranial PSI Accessories demonstrate biocompatibility consistent with current consensus standards.
    - Plastic Drawing Guide demonstrates resistance to deformation in excess of loading applied in clinical use.