October 1, 2021

OssDsign AB
% David Weissburg
Weissburg Associates
411 Walnut Street #16642
Green Cove Springs, Florida 32043-3443

Re: K212414
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: July 30, 2021
Received: August 3, 2021

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,

Adam D. Pierce, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212414

Device Name
OSSDSIGN Cranial PSI

Indications for Use *(Describe)*
OSSDSIGN Cranial PSI is an implant intended for the reconstruction of cranial defects. These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The ceramic component of Cranial PSI resorbs and is replaced with bone during the healing process. Cranial PSI is indicated for use in 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K212414

1. 510(k) Owner Name and Address:
   OSSDSIGN AB
   Rapsgatan 23A
   SE 754 50, Uppsala
   Sweden
   Telephone: +46 (0) 18-55 39 93
   Email: ja@ossdsign.com
   Contact: Jonas Åberg

2. Contact Person:
   David Weissburg
   Weissburg Associates
   411 Walnut Street #16642
   Green Cove Springs, FL 32043-3443
   USA

3. Date prepared: October 1, 2021

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. Predicate Device: OSSDSIGN Cranial PSI (K161090)

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 component of Cranial PSI resorbs and is replaced with bone during the healing process. 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 an implant intended for the reconstruction of cranial defects. These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The ceramic component of Cranial PSI resorbs and is replaced with bone during the healing process. Cranial PSI is indicated for use in 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:
    The subject device is identical to cleared predicate device OssDsign Cranial PSI K161090 in every way except the proposed labeling change.

	OSSDSIGN Cranial PSI (K212414, subject device)	OSSDSIGN Cranial PSI (K161090, predicate)
Indications For Use	OSSDSIGN Cranial PSI is an implant intended for the reconstruction of cranial defects. These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The ceramic component of Cranial PSI resorbs and is replaced with bone during the healing process. Cranial PSI is indicated for use in 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	Ti grade 23, proprietary calcium phosphate ceramic	Ti grade 23, proprietary calcium phosphate ceramic
Titanium thickness	0.4 – 1.6 mm	0.4 – 1.6 mm
Max size	200 cm^2	200 cm^2
Provided form	Titanium and Ceramic Ceramic mixed and cured in manufacturer's facility	Titanium and Ceramic Ceramic mixed and cured in manufacturer's facility
Sterility on delivery	Sterile	Sterile

12. Performance Testing:

Test	**Test Method Summary**	**Results**
in vivo implantation	52-week sheep implantation study, ISO 10993-6	*in vivo* studies show biocompatibility, adequate resorption rate and osteoconduction.

13. Conclusion:

Nonclinical tests demonstrate that Cranial PSI is as safe and effective as its legally marketed predicate device.