October 12, 2018

OssDsign AB
% David Weissburg
Prinicpal
Weissburg Associates
808 Williamson St., Suite 402
Madison, Wisconsin 53703

Re: K181539
Trade/Device Name: OSSDSIGN Cranioplug
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: September 10, 2018
Received: September 11, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181539

Device Name
OSSDSIGN Cranioplug

Indications for Use *(Describe)*
OSSDSIGN Cranioplug is an implant intended to cover and plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery. These osseous defects are surgically created and are not intrinsic to the stability of the bony structure. The ceramic component of Cranioplug resorbs and is replaced with bone during the healing process. Cranioplug is indicated for use in adults and adolescents age 12 and older.

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

K181539

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

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

3. Date prepared: October 10, 2018

4. Trade Name: OSSDSIGN® Cranioplug

5. Regulation Description: Burr Hole Cover

6. Classification Name: Cover, Burr Hole (21 CFR 882.5250, Product Code GXR)

7. Class: 2

8. Predicate: K140309, Cranioplug, OssDsign

9. Device Description: OSSDSIGN Cranioplug003 is an osteoconductive calcium phosphate ceramic plug reinforced with a titanium mesh plate which together provide the mechanical performance, safety and efficacy properties. The fully cured calcium phosphate ceramic fills the void in the burr hole. The osteoconductive ceramic component of Cranioplug resorbs and is replaced with bone during the healing process. Cranioplug is sized to match standard 11mm and 14mm burr hole perforators.

10. Intended Use / Indications For Use: OSSDSIGN Cranioplug is an implant intended to cover and plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery. These osseous defects are surgically created and are not intrinsic to the stability of the bony structure. The ceramic component of Cranioplug resorbs and is replaced with bone during the healing process. Cranioplug is indicated for use in adults and adolescents age 12 and older.

11. Comparison of Technological Characteristics with the Predicate Device:

	OSSDSIGN Cranioplug003 (subject device)	OSSDSIGN Cranioplug001 (Predicate, K140309)
Intended Use	OSSDSIGN Cranioplug is an implant intended to cover and plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery. These osseous defects are surgically created and are not intrinsic to the stability of the bony structure. The ceramic component of Cranioplug resorbs and is replaced with bone during the healing process. Cranioplug is indicated for use in adults and adolescents age 12 and older.	OSSDSIGN Cranioplug is intended to cover and plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery. It is cleared for use for non-weight bearing applications in adults and adolescents age 12 and older.
Materials	Ti grade 2, proprietary calcium phosphate formulation (same as predicate)	Ti grade 3, proprietary calcium phosphate formulation
Re-sterilizable	No	No
Titanium thickness	0.4mm	0.5mm
Sizes (diameter)	11mm and 14mm	14mm
Ceramic hardening	Cured in manufacturer's facility	Cured in manufacturer's facility
Sterility on delivery	Sterile	Sterile
Shelf life	24 months	18 months

12. Testing vs. predicate: Cranioplug003 and its predicate were tested for bench performance characteristics and biologic performance. Direct comparison of performance, safety and effectiveness of Cranioplug003 and its predicate demonstrates that Cranioplug003 is substantially equivalent to its predicate in all characteristics. The table below provides a summary of some of the tests completed.

Test	Test Method Summary	Results
Energy absorption, flap reattachment	Device and predicate installed in anatomical model. Tested in Universal Testing Machine to 2mm displacement to determine deformation energy.	Subject device and predicate sustained deformation energy of 0.06 J.
Flap Fixation Dynamic Load	Flap fixated with 3 Cranioplugs installed in anatomic model. 8.5 kg head weight tested to simulate 50 years of sleep with hourly repositioning.	No flap deformation. All Cranioplug models tested.
Cytotoxicity	ISO elution method, ISO 10993-5, extracted in IX MEM at 37°C for 24 hours	No evidence of causing cell lysis or toxicity.
in vivo implantation	52-week sheep implantation study, ISO 10993-6	*in vivo* studies show biocompatibility, adequate resorption rate and osteoconduction.

13. Conclusions: Nonclinical tests demonstrate that Cranioplug003 is as safe and effective as its legally marketed predicate device.