July 27, 2018

Oxford Performance Materials, Inc.
M. Beth Pashko
Quality Director
30 South Satellite Road
South Windsor, Connecticut 06074

Re: K180064
Trade/Device Name: OsteoFab Patient Specific Cranial Device
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: June 29, 2018
Received: July 2, 2018

Dear Ms. Pashko:

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,

Valerie A. Flournoy -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)*
K180064

Device Name
OsteoFab Patient Specific Cranial Device

Indications for Use *(Describe)*
The OsteoFab Patient Specific Cranial Device (OPSCD) is intended for the replacement of bony voids in the cranial skeleton. OPSCDs may be used to fit pre-planned virtual defects in the instance of single stage cranioplasty procedures.

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 [As required by 21 CFR 807.92]

I. Submitter

510(k) Owner:	Oxford Performance Materials, Inc. 30 South Satellite Road South Windsor, CT 06074 USA Phone: +1.860.698.9300 Fax: +1.860.698.9978
Submitter/Contact:	M. Beth Pashko Quality Director Oxford Performance Materials, Inc. 30 South Satellite Road South Windsor, CT 06074 USA Phone: +1.860.698.9300
Date Prepared:	June 29, 2018

II. Device

Proprietary Name:	OsteoFab® Patient Specific Cranial Device
Common or Usual Name:	Patient Specific Cranial Implant
Classification:	21 CFR 882.5330; Preformed non-alterable cranioplasty plate
Regulatory Class:	Class II
Product Code:	GXN
Review Panel:	Neurology

III. Predicate Device

Predicate Device:	Oxford Performance Materials, Inc. OsteoFab® Patient Specific Cranial Device (K121818)

IV. Device Description

An OsteoFab® Patient Specific Cranial Device (OPSCD) is built individually for each patient to correct defects in cranial bone. OPSCDs are constructed with the use of the patient's CT scan and computer aided design is used to determine the geometry of each implant. OPSCDs are built by laser sintering polyetherketoneketone (PEKK) polymer in Oxford Performance Materials' OsteoFab® process. OPSCDs are attached to native bone with commercially available cranioplasty fixation systems and are a non-load bearing, single use device. OPSCDs are provided non-sterile.

Oxford Performance Materials
30 South Satellite Road • South Windsor, CT 06074 USA • T: +1.860.698.9300 • F: +1.860.698.9978 • www.oxfordpm.com

Indications for Use

The OsteoFab® Patient Specific Cranial Device (OPSCD) is intended for the replacement of bony voids in the cranial skeleton. OPSCDs may be used to fit pre-planned virtual defects in the instance of single stage cranioplasty procedures.

V. Comparison of Technological Characteristics with the Predicate Device

Principle of Operation

The basic operational principle of the OPSCD remains the same as the predicate: the operating principle of the OPSCD is to replace bony voids in the cranial skeleton.

Technological Characteristics

New performance data was required to ensure that OPSCDs can be used successfully in pre-planned defects in addition to existing cranial bone defects. The technological characteristics remain the same and are summarized below.

- Same operating principle: to replace bony voids in the cranial skeleton
- Same material: there is no change to the implant material
- Same manufacturing process: laser sintering of PEKK polymer
- Same sterilization method: there is no change in the implant sterilization method
- Similar design process: there is no change to the implant design process. Surgeons may now provide single-stage design inputs for the scope of the implant reconstruction boundary
- Same mode of fixation: commercially available cranioplasty fixation systems

VI. Performance Data

The modifications described in this submission include a clarification to the device Warnings based on the prescribed Indications for Use. There are no changes to the device specifications, manufacturing process, or operating principle of the OPSCD. The following performance data were provided in support of the substantial equivalence determination based on the risk analysis that was performed.

Performance Bench Testing

The following performance bench test was completed:

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Test	Test Method Summary	Results
End-to-End Simulation Report for OPSCD for Single Stage Surgery The purpose of this test was to verify the process of using OPSCDs for single stage cranioplasty procedures, that is, where the defect is not present at the time of the CT scan.	Worst-case, representative cranial cases were selected for end-to-end simulation testing. Implants were designed to the specifications cleared in K121818, manufactured using the same process, inspected, shipped, and fit tested on skull models. Fit testing was conducted using commercially available marking guides, as is typical in single stage cranioplasties. Acceptance criteria included meeting existing product release criteria, successful shipment without damage to the devices, successful fixation of the implants onto the skull models, and satisfactory fit.	All acceptance criteria were met, showing that OPSCDs used in single stage cranial surgeries can successfully fill a defect that did not exist prior to the surgical procedure, that is, OPSCDs may be designed to fit pre-planned virtual defects and function as intended. Based on these results, the OPSCD is considered as safe and as effective as the predicate device and performs as well as the marketed predicate device.

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing

Clinical testing was not required as a basis for substantial equivalence.

VII. Substantial Equivalence Conclusion

Enabling surgeon design inputs for single stage procedures does not impact the safety or effectiveness of the device per the results of the non-clinical data. The summarized performance testing supports that the OsteoFab® Patient Specific Cranial Device is as safe and as effective as the predicate device and that it performs as well as the marketed predicate device in the prescribed indications. The technological principles of the subject device are unchanged and are substantially equivalent to the predicate device, according to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein.

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