DEPARTMENT 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

July 20, 2016

Oxford Performance Materials, Inc.
Ms. Leigh Ayres
SRA Director
30 S. Satellite Road
South Windsor, CT 06074

Re: K161052
Trade/Device Name: OsteoFab Patient Specific Facial Device
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: Class II
Product Code: KKY
Dated: June 22, 2016
Received: June 23, 2016

Dear Ms. Ayres:

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" (21CFR 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K161052

Device Name
OsteoFab® Patient Specific Facial Device

Indications for Use *(Describe)*
The OsteoFab® Patient Specific Facial Device (OPSFD) is designed individually for each patient for enhancement, to correct trauma, and/or to correct defects in facial bone. The OPSFD is also designed individually for non-load bearing enhancement of mandibular bone.

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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OPSFD 510(k) Summary as Required by Title 21 CFR 807.92

510(k) Submitter: Oxford Performance Materials, Inc.
P.O. Box 585
30 South Satellite Road
South Windsor, CT 06074
1-860-698-9300

Contact Person: Leigh Ayres, Director of Scientific and Regulatory Affairs
Date of 510(k) summary statement preparation: July 12, 2016
Proprietary name: OsteoFab® Patient Specific Facial Device
Common or Usual Name: Polytetrafluoroethylene (PTFE) with Carbon Fibers
Classification: 878.3500 General/Plastic Surgery
Review Panel: General/Plastic Surgery
Medical Device Classification: Class II
Product Code: KKY
Predicate Device: Oxford Performance Materials, Inc. OsteoFab® Patient Specific Facial Device (K133809)

Description of the Device

HTR-PEKK is a custom implant and the shapes and sizes vary within the following specifications: (1) maximum diameter is 20cm (2) minimum thickness is 1mm (2mm in areas of fixation), (3) maximum thickness is 20mm and the maximum thickness for holes is 10mm, (4) maximum open density is 25%, (5) minimum as designed through-hole diameter is 3mm, (6) maximum as designed though-hole size must meet these specifications (7) minimum distance from the edge of an as designed through-hole (for a cluster of perfusion-holes) to the edge of a device is 15mm, (8) minimum distance from the center of an as designed dimple to the edge for plating is 2.5mm for a 1.5mm diameter screw, (9) minimum distance from the center of an as designed dimple to the edge for lagging is 2.5mm for a 1.5mm diameter screw, (10) minimum distance between two lag holes is 3.25mm for a 1.5mm diameter screw, (11) minimum distance from the center of an as designed dimple to the edge for lagging is 3.75mm for a 2mm diameter screw, and (12) minimum distance between two lag holes is 3.75mm for a 2mm diameter screw.

Note: number 7 regarding as designed holes was changed to add a qualifier based on the context of that configuration of through-holes.

The OPSFD is constructed with the use of the patient's CT imaging data and computer aided design to determine the dimensions of each implant. The OPSFD is built by a LASER sintering machine. The OPSFD is attached to native bone with commercially available fixation systems. The OPSFD is a non-load bearing single use device and it is shipped non-sterile.

Intended Use Statement

The OsteoFab® Patient Specific Facial Device (OPSFD) is designed individually for each patient for enhancement, to correct trauma, and/or to correct defects in facial bone. The OPSFD is also designed individually for non-load bearing enhancement of mandibular bone.

Description of the Modifications

The description in the labeling is the same as the description that was submitted in K133809 except the following changes were made:

1. Implant minimum thickness was amended (number 2).
2. Implant maximum thickness was increased (number 3).
3. The minimum through-hole diameter was defined in terms of an as designed instead of an as built specification (number 5).
4. The maximum through-hole diameter was defined in terms of an as designed instead of an as built specification that must meet all of the specifications in the device description section (number 6).
5. A qualification statement for the minimum edge distance regarding a cluster of perfusion-holes was added (number 7).
6. The minimum as designed edge distance for plating was added (number 8).
7. The minimum as designed edge and through-hole center to center distances for lagging were added (numbers 9, 10, 11, and 12).

The following additions were made to the Warnings section of the IFU for this Special 510(k):

8. Screw fixation for plating or lagging should be placed only in areas of an implant that has minimum thickness of a 2mm (number 1).
9. The Surgeon should take special care if contouring is needed in areas where there is going to be fixation regarding implant thickness and distance to the edge (number 5).

The warnings regarding fixation and contouring were derived from the results of the performance testing.

Performance Data and Risk Analysis

New performance data was not required for changing the specifications from "as built" to "as designed" because the change was a correction. New performance data was not needed for

the change to the maximum though-hole specification because it was a correction - the 5mm test specification had been included in the K133809 evaluation as an aid to determine the minimum though-hole size.

New performance data was not required regarding the qualifier that was added for the 15mm edge specification. Performance data was not required because the qualifying statement regarding a cluster of through-holes provided clarity to the device description to insure safer or more effective use. The statement about the cluster of though-holes provided clarity because the intent of that specification is to provide a margin of safety for the location of though-holes when they could be near to the location of dimples that are utilized for fixation procedures.

The changes in the package insert for implant thickness and fixation (plating and lagging) required new non-clinical performance data based on the results obtained from risk analysis. Risks were calculated according to the severity, probability, and detectability of failure modes.

The new performance data was submitted in the Special 510(k) for implant thickness and fixation in order to verify and validate the changes to the package insert. The data obtained was proof of performance.

Substantial Equivalence Conclusion

The modifications to the description and warnings of the labeling for the subject device are substantially equivalent to the predicate device.