OPM

5 - OPSFD 510(k) Summary Statement as Required by Title 21 CFR 807.92(c)

510(k) Submitter: Oxford Performance Materials, Inc.
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Contact Person: Leigh Ayres, Director of Scientific and Regulatory Affairs
Date of 510(k) summary statement preparation: July 21, 2014
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 Devices: Polyclinic Medical Center Hard Tissue Replacement (HTR) Patient Matched Implant (K924935), the Synthes SynPOR HD Porous Polyethylene (K111323), and the Stryker® Patient Specific Polymer Implant (K103010)

Description of the Device

An OsteoFab® Patient Specific Facial Device (OPSFD) is built individually for each patient. The OPSFD is made of polyetherketoneketone (PEKK) polymer and built by a LASER sintering machine. 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. OPSFDs come in a variety of configurations that depend on the geometry of the application. OPSFDs are oblong and (for an individual patient) have shapes and sizes that vary within the following specifications: (1) maximum diameter is 20 cm (2) minimum thickness is 1 mm, (3) maximum thickness is 10 mm, (4) maximum open density is 25%, (5) minimum as built hole diameter is 3 mm, (6) maximum as built hole diameter is 5 mm, and (6) minimum distance from the edge of an as built hole to the edge of a device is 15 mm.

The OPSFD is attached to native bone with commercially available fixation systems and it is a permanent implant. The OPSFD is a non-load bearing single use device and it does not impart mechanical strength to the implant area. The OPSFD implant is shipped non-sterile and the sterilization recommendations documented in the instructions for use (IFU) are according to ANSI/AAMI ST79 "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" have been validated. The validation for gravity displacement steam sterilization

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was conducted at 135°C (275°F) with a half cycle of five (5) minutes. The validation for prevacuum steam sterilization was conducted at 132°C (270°F) with a half cycle of two (2) minutes.

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.

Biocompatibility

Biocompatibility tests were selected according to the FDA guidance document: "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (1995) and the test results obtained from PEKK test specimens were found to be within acceptance criteria described in the ISO 10993-3, 5, 6, 10, 11, and 18 standards.

The results of cytotoxicity testing on OsteoFab® test specimens utilizing L-929 mouse fibroblast cells or human neuroblastoma SK-N-MC cells were within ISO 10993-5 acceptance criteria.

The Limulus Amebocyte Lysate method was performed on OsteoFab® test specimens to evaluate bacterial endotoxin utilizing the Gel-Clot method according to USP 85. The test results were below the medical device contacting cerebral spinal fluid acceptance criterion (<2.15 EU/Device).

Performance Testing – Bench Testing

QUALITY CONTROL

The test suite for the final quality control (QC) testing of the OsteoFab® Patient Specific Facial Device (OPSFD) builds includes glass transition temperature (Tg), Fourier transform infrared spectroscopy (FTIR), specific gravity, and tensile strength. This is the same QC testing that is performed when an OsteoFab® Patient Specific Cranial Device (OPSCD) is manufactured. The OPSCD device was cleared by the FDA on February 7, 2013 (K121818).

The final QC specifications for those tests were determined from 32 builds. TABLE 18.A shows the mean, the standard deviation, the standard deviation multiplied by 3, the acceptance criteria, and the formula for the acceptance criteria.

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TABLE 18.A: Summary Statistics of 32 Builds

	Tg (20°C/min)	FTIR	Average Specific Gravity	Average Tensile Stress at Break (X-orientation) (KPSI)	Average Tensile Elongation @ Break (%)	Average Young's Modulus of Elasticity (KPSI)
mean	158.16	98.11	1.29	11.67	2.63	509.09
SDEV	0.51	1.16	0.0072	0.89	0.39	75.93
3SD	1.53	3.48	0.022	2.67	1.17	227.79
Acceptance Criteria	157-160	≥ 95% Match	1.27-1.31	≥ 9.0	≥ 1.5	≥ 281
Formula for the Acceptance Criteria	Mean +/- 3SD	≥ 95% Match to a designated PEKK standard	Mean +/- 3SD	Mean - 3SD	Mean - 3SD	Mean - 3SD

The test specimens from the 32 builds that were subjected to tensile strength testing were 3.2 mm thick.

WALL THICKNESS AND THROUGH HOLE SIZE

In order to determine the minimum wall thickness for an OPSFD implant, three sets (5 specimens each) of tensile bars that were 1, 2, and 4 mm thick were built. The average tensile strength data for each size is compared to the final QC release acceptance criteria (see TABLE 18.B).

All three sizes (1, 2, and 4 mm) of test specimens are substantially equivalent to the 3.2 mm final QC test specimen because the data obtained was within the final QC acceptance criteria (see TABLE 18.B). Based on the measurements obtained, the minimum allowable thickness of an OPSFD implant is 1 mm.

TABLE 18.B: Summary Statistics of the 1, 2, and 4 mm Thick Test Specimens

Sample Description	Average Tensile Stress at Break (X-orientation) (KPSI)	Average Tensile Elongation @ break (%)	Average Young's Modulus of Elasticity (KPSI)
1 mm thickness (average)	10.5	2.4	329
2 mm thickness (average)	10.8	2.4	409
4 mm thickness (average)	11.6	2.4	490
Release Criteria for 3.2 mm thickness	≥ 9.00	≥ 1.5	≥ 281

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The tensile testing was conducted according to ASTM D638 "Standard Test Method for Tensile Properties of Plastics."

Test specimens were also built to determine the range of pore (through holes) sizes and the minimum spacing of through holes. These test specimens were 4 mm thick and each had more than 10 through holes. Based on the measurements obtained, the range of through holes that can be built with the P-800 is 2 mm to 5 mm and the minimum spacing of through holes is 2 mm. TABLE 18.C and TABLE 18.D show the average of the through hole size measurements and the average of the spacing between through hole measurements, respectively.

TABLE 18.C: Vernier Caliper Measurements of the Diameter of Through Holes

	5 mm Through Hole Test Specimen with 5 mm Spacing (Diameter in mm)	2 mm Through Hole Test Specimen with 2 mm Spacing (Diameter in mm)
Average (n=10)	4.74	1.92
Standard Deviation	0.03	0.05
Nominal Value with Tolerance	5.00 (4.50 – 5.50)	2.00 (1.50 – 2.50)

TABLE 18.D: Vernier Caliper Measurements of the Spacing between Through Holes

	5 mm Through Hole Test Specimen with 5 mm Spacing (Spacing in mm)	2 mm Through Hole Test Specimen with 2 mm Spacing (Spacing in mm)
Average (n=10)	4.81	1.79
Standard Deviation	0.02	0.03
Nominal Value with Tolerance	5.00 (4.50 – 5.50)	2.00 (1.50 – 2.50)

SCREW INSERTION

There were two experiments conducted to evaluate the effect of applying screws to PEKK test blocks: manually apply self-drilling screws and manually apply self-tapping screws after drilling a pilot hole.

The PEKK test blocks were 3 mm thick and had a straight edge or an edge that had a 45° angle. Each test block had 14 fingers. The PEKK test blocks were made from a build that had the job number 2634. After drilling, the screws and plates were removed and the PEKK test blocks were inspected with a 10x magnification eye loop.

Each screw (1.5 mm diameter x 4 mm) was driven into first a Thinflap plate and second into a finger of the test block. The distance between the edge of the PEKK test block and the tangent of the screw nearest to the edge was 3 mm.

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The results of the self-drilling experiment were as follows:

1. Fractures for the straight edge were 0/28.
2. Fractures for the 45° angle edge were 2/28.

The results for the self-tapping experiment were as follows:

3. Fractures for the straight edge were 0/28.
4. Fractures for the 45° angle edge were 0/28.

DROP CHARACTERIZATION

(The test specimens utilized for this study were not from the steam sterilization validation evaluation of the IFU recommendations.)

There were three experiments conducted to evaluate the effect of dropping PEKK test specimens from four feet above the floor. The PEKK test specimens were in a cranial flap configuration (job number 2724). The PEKK test specimens were dropped horizontally in the dome up position, horizontally in the dome down position, and vertically.

The test specimens N=1 for each experiment were first steam sterilized at 134°C for 4 minutes and then dried for 30 minutes. The material loss from all three experiments was equal to or less than 0.020%. The results from the three experiments are summarized on TABLE 18.K.

TABLE 18.K: Drop Test Results

SEQ	Experiment Description	Percent Difference (loss) in Test Specimen Weight (grams)	Results of 10x Inspection
1.	Horizontal, dome up	0.017/84.036 * 100 = 0.020%	Slight indentation on the point of impact
2.	Horizontal, dome down	0.002/84.736 * 100 = 0.002%	Slight indentation on the point of impact
3.	Vertical	0.007/84.418 * 100 = 0.008%	Slight indentation on the point of impact

EDGE DISTANCE

(The test specimens utilized for this study were not from the steam sterilization validation evaluation of the IFU recommendations.)

There were four experiments conducted to evaluate the effect of applying screws to PEKK test blocks. The experimental conditions, inspections, and the results of the inspections for each of the four experiments are shown on TABLE 18.L.

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There were 45/45 fingers in the PEKK test blocks (job 2843) in the Rev B evaluation that did not have cracks.

There were 45/45 fingers in the PEKK test blocks (job 2849) in the Rev D evaluation that did not have cracks.

Each experiment utilized PEKK test blocks (each had fourteen fingers).

TABLE 18.L: LT1274 Summary of Experimental Conditions and Test Results

SEQ	Rev A: Test Sequence/Results	Rev B: Test Sequence/Results	Rev C: Test Sequence/Results	Rev D: Test Sequence/Results
1.	Inspect 10x magnification: pass	Inspect 10x magnification: pass	Inspect 10x magnification: pass	Inspect 10x magnification: pass
2.	Three PEKK job 2820 Test Blocks 3 mm thick, 45° edge	Four PEKK job 2843 Test Blocks 3 mm thick, 45° edge	One PEKK job 2849 Test Blocks 3 mm thick, 45° edge	Four PEKK job 2849 Test Blocks 3 mm thick, 45° edge
3.	132°C (4 min) dry (30 min) x 1	132°C (4 min) dry (30 min) x 1	132°C (4 min) dry (30 min) x 1	132°C (4 min) dry (30 min) x 1
4.	Inspect 10x magnification: pass	Inspect 10x magnification: pass	Inspect 10x magnification: pass	Inspect 10x magnification: pass
5.	Pre-drill 1.1 mm Drill with 5 mm stop at 3.75 mm (Screw Centerline to Edge) x 45	Pre-drill 1.1 mm Drill with 5 mm stop at 5 mm (Screw Centerline to Edge) x 45	No pre-drilling	No pre-drilling
6.	Overlay 2-hole 1.5 thin plate	Overlay 2-hole 1.5 thin plate	Overlay 2-hole 1.5 thin plate	Overlay 2-hole 1.5 thin plate
7.	Manually add 1.65 mm diameter x 5 mm High Torque Screws and do not strip out	Manually add 1.65 mm diameter x 5 mm High Torque Screws and do not strip out	Manually add 1.5 mm diameter x 4 mm High Torque Screws and do not strip out at 5 mm (Screw Centerline to Edge) x 45	Manually add 1.5 mm diameter x 4 mm High Torque Screws and do not strip out at 7 mm (Screw Centerline to Edge) x 45
8.	Remove screws	Remove screws	Remove screws	Remove screws
9.	Results of 10x magnification Inspection: 4/45 cracked	Results of 10x magnification Inspection: 45/45 no cracks	Results of 10x magnification Inspection: 1/6 cracked – the study was discontinued	Results of 10x magnification Inspection: 45/45 no cracks

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MODIFICATION

(The test specimens utilized for this study were not from the steam sterilization validation evaluation of the IFU recommendations.)

There were three experiments conducted to evaluate the effect of modifying PEKK test specimens. The PEKK test specimens were in a cranial flap configuration (job number 2823).

The first experiment evaluated edge modification utilizing a power tool and a diamond burr or a deep flute burr. Each burring method was applied with light pressure and heavy pressure.

The second experiment evaluated re-contouring utilizing a power tool and a diamond burr or a deep flute burr. Each re-contouring method was applied with light pressure and heavy pressure.

The third experiment evaluated cutting with a power tool and a sagittal saw or a reciprocating saw.

The test specimens N=2 for each experiment were first steam sterilized at 134°C for 4 minutes and then dried for 30 minutes.

The results from the three experiments are summarized on TABLE 18.M.

TABLE 18.M: Test Results from Modifying PEKK Test Specimens

SEQ	Experiment Description	Characteristic Measured	Characteristic Measured
1.	Edge Modification	Diamond burr light pressure: No issues were observed with both test specimens.	Diamond burr heavy pressure: The debris material surrounding the cut melted due to friction for both test specimens.
2.	Edge Modification	Deep flute light pressure: No problems were observed with both test specimens.	Deep flute heavy pressure: The deep flute burr head was unstable for both test specimens.
3.	Re-contouring	Diamond burr light pressure: The burr cut the surface very well with both test specimens.	Diamond burr heavy pressure: The debris material surrounding the cut melted due to friction for both test specimens.
4.	Re-contouring	Deep flute light pressure: No problems were observed with both test specimens.	Deep flute heavy pressure: The deep flute burr head was unstable for both test specimens.

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SEQ	Experiment Description	Characteristic Measured	Characteristic Measured
5.	Cutting	Sagittal saw: Edge cutting was easy for both test specimens. Surface cutting was not as easy for both test specimens.	Reciprocating saw: Edge and surface cutting was easy for both test specimens.

DIMENSIONAL STABILITY

(The test specimens utilized for this study were not from the steam sterilization validation evaluation of the IFU recommendations.)

Ten test specimens in a cranial flap configuration were subjected to three steam sterilization cycles. The part numbers were IG2823M-8F001 to IG2823M-8F010. All ten test specimens were steam sterilized at 134°C for 4 minutes. All ten test specimens were scanned with a Romer arm prior to sterilization.

After each sterilization cycle, the ten test specimens were cooled for 30 minutes prior to dimensional analysis by a Romer arm scanner. An eye loop that had a 10x magnification was utilized to inspect all 10 test specimens after each sterilization cycle.

The following results were obtained:

1. After each of the three sterilization cycles and for each test specimen, 99% or more of the datum points collected during the Romer arm scans were within ± 0.005 inches of the datum points collected from the pre-sterilization Romer arm scans.
2. No cracking, fracturing, swelling, or shrinkage was observed in any of the test specimens.

Ten test specimens in a cranial flap configuration were subjected to nine steam sterilization cycles. The part numbers were IG2823M-8F001 to IG2823M-8F010. The first three steam sterilization cycles were conducted at 134°C for 4-8 minutes. The second three steam sterilization cycles were conducted at 134°C for 4 minutes. The third three steam sterilization cycles were conducted at 137°C for 18 minutes.

A Romer arm was utilized to scan all ten test specimens before and after nine sterilization cycles. An eye loop that had a 10x magnification was utilized to inspect all 10 test specimens after the ninth sterilization cycle.

The following results were obtained:

3. After the ninth sterilization cycle, 99% or more of the datum points collected by the Romer arm from each of the ten test specimens were within ± 0.005 inches of the pre-sterilization Romer arm datum points.

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4. No cracking, fracturing, swelling, or shrinkage was observed in the test specimens after nine sterilization cycles.

AXIAL PULLOUT FORCE AND PREDICATE COMPARISONS

(The test specimens utilized for this study were not from the steam sterilization validation evaluation of the IFU recommendations.)

There were four experiments conducted to evaluate axial pullout force. The first and the fourth experiments included the evaluation of materials that are utilized for the manufacture of predicate devices.

For the first experiment, PEKK test specimens were steam sterilized once at 134°C for four minutes and dried for 30 minutes and the PMMA test specimens were gamma sterilized once between 26.2 and 31.9 kilo Grays.

For the second experiment, PEKK test specimens were steam sterilized at 134°C for four minutes and dried for 30 minutes. All 12 test specimens were sterilized once. Eight test specimens were sterilized twice and four test specimens were sterilized three times. Repeat sterilizations were conducted to evaluate the stability of the PEKK test specimens.

For the third experiment, PEKK test specimens were steam sterilized at 137°C for 18 minutes and dried for 30 minutes. All 12 test specimens were sterilized once. Eight test specimens were sterilized twice and four test specimens were sterilized three times. Repeat sterilizations were conducted to evaluate the stability of the PEKK test specimens.

For the fourth experiment, ten PEEK test specimens were steam sterilized once at 134°C for four minutes and dried for 30 minutes.

After sterilization, each of the four experiments had all test specimens pre-drilled in two locations utilizing a 1.1 mm diameter drill that had a 5 mm stop. After pre-drilling, 1.5 mm diameter x 3.5 mm screws were manually driven into each combination of screw grip fixture and the pre-drilled through holes on each test specimen.

Each of the four experiments were conducted according to ASTM F543-07, "Standard Specification and Test Method for Metallic Medical Bone Screws, Annex A3: Test Method for determining the Axial Pullout Strength of Medical Bone Screws." The results are shown on TABLE 18.N.

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TABLE 18.N: Summary from the LT1294, LT1295, and LT1296 Evaluations of PMMA (Poly(methyl methacrylate), PEKK (polyetherketoneketone) and PEEK (polyetheretherketone) Test Specimens

SEQ	Test Specimen/Report Number	N (Sample Size)	Mean Peak Axial Pullout Force (Newtons)	Standard Deviation	Coefficient of Variation (%)	Sterilization method/ Number of cycles
1.	PMMA/LT1294	20	43.5	16.2	37	Gamma x 1
2.	PEKK/LT1294	10	244.0	32.1	14	Steam x 1
3.	PEKK/LT1294	10	227.1	28.0	12	Steam x 1
4.	PEKK/LT1295 Rev A	8	233.1	11.0	5	Steam x 1
5.	PEKK/LT1295 Rev A	8	233.1	23.6	10	Steam x 2
6.	PEKK/LT1295 Rev A	8	207.5	27.9	13	Steam x 3
7.	PEKK/LT1295 Rev B	8	196.2	68.1	35	Steam x 1
8.	PEKK/LT1295 Rev B	8	222.0	55.2	25	Steam x 2
9.	PEKK/LT1295 Rev B	8	226.4	73.8	33	Steam x 3
10.	PEEK/LT1296	20	193.6	27.5	14	Steam x 1

All test specimens had the same failure mode "the screw pulled out of material" at the peak axial pullout force. PEKK test specimens were stronger than the PMMA test specimens and the PEEK test specimens.

TENSILE STRENGTH PEKK DATA VERSUS A PMMA STANDARD

A comparison table of tensile strength was prepared in order to assess substantial equivalence between the (1) subject device OPSFD manufactured from OsteoFab® and (2) predicate devices made from PMMA. TABLE 18.O shows the acceptance criteria for tensile strength derived from QC data obtained from OsteoFab® test specimens that represent the subject device (see also TABLE 18.A). TABLE 18.O also shows tensile strength values published in the ASTM D4802 document "Standard Specification for PMMA."

TABLE 18.O: Comparison Table of Tensile Strength

Characteristic Measured	Acceptance Criteria for OPSFD Calculated from N=32 Test Specimens	Nominal values obtained from PMMA test specimens according to ASTM D4802
Tensile at Break	ASTM D638 QMSP-1067 (OPSFD) ≥ 9,000 psi	ASTM D638 9,000 psi
Elongation at Break	ASTM D638 QMSP-1067 (OPSFD) ≥ 1.5 %	ASTM D638 2%

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The PEKK and PMMA materials, based on tensile strength, are substantially equivalent because:

1. The PMMA and PEKK test specimens were prepared and tested according to ASTM D638 "Standard Test Method for Tensile Properties of Plastics."
2. The PMMA nominal value for tensile at break is the same value as the QC acceptance criterion for OsteoFab® test specimens.

3. The 2% elongation at break for PMMA is within the acceptance criterion for OsteoFab® test specimens.

Substantial Equivalence Discussion

The OsteoFab® Patient Specific Facial Device (OPSFD) is substantially equivalent in safety and effectiveness to three other predicate devices cleared by the FDA under Title 21 CFR 878.3500 polytetrafluoroethylene with carbon fibers composite implant material. Those three predicate devices are: the Polyclinic Medical Center Hard Tissue Replacement (HTR) Patient Matched Implant (K924935), the Synthes SynPOR HD Porous Polyethylene (K111323), and the Stryker® Patient Specific Polymer Implant (K103010). Information about the predicate devices was obtained from 510(k) summary statements and/or the 510(k) FDA Access Database.

The intended use statement for the OPSFD is within the scope of the intended use statements for the Synthes and Stryker® devices. The intended use statements encompass enhancement, to correct trauma, and/or to correct defects in the in mandibular, maxillofacial, or craniofacial bone. The intended use statement for the Polyclinic Medical Center HTR Patient Matched Implant was not available in the sources described above.

All three devices are fabricated from polymers. The OPSFD and Stryker® Patient Specific Polymer Implant are custom manufactured using patient CT data. The sources described above did not include information about the manufacturing processes for Synthes SynPOR or Polyclinic Medical Center HTR.

The sources described above did not include information about biocompatibility evaluations for the predicates. The test results obtained from OPSFD test specimens were found to be within ISO 10993-3, 5, 6, 10, 11, and 18 acceptance criteria and the endotoxin values obtained were below the medical device contacting cerebral spinal fluid acceptance criterion (<2.15 EU/Device).

The OPSFD is not porous. The Synthes and Stryker® implant devices are described as porous.

The OPSFD is shipped non-sterile in packaging that is ISTA 2A compliant. The OPSFD instructions for use describe validated steam sterilization procedures. The Synthes and Stryker® devices are shipped as sterile medical devices. Sterile packaging validation was listed for the Synthes predicate.

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The substantial equivalence information on the subject and predicate devices is summarized on the substantial equivalence chart. The substantial equivalence chart shows that the characteristics listed for the subject (OPSFD) and the three predicate devices are substantially equivalent.

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Substantial Equivalence Chart: Information about the predicate devices was obtained from 510(k) summary statements and/or the 510(k) FDA Access Database

Characteristic	Subject Device (OPSFD)	Stryker® Patient Specific Polymer Implant (K103010)	Synthes SynPOR HD Porous Polyethylene (K111323)	Polyclinic Medical Center Hard Tissue Replacement (HTR) Patient Matched Implant (K924935)
Manufacturer	Oxford Performance Materials	Stryker® Howmedica Osteonics	J&J DePuy Synthes	Biomet Microfixation
Regulation Number	878.3500 General/Plastic Surgery	878.3500 General/Plastic Surgery	878.3500 General/Plastic Surgery	878.3500 General/Plastic Surgery
Regulation Name	Polytetrafluoroethylene (PTFE) with Carbon Fibers	Polytetrafluoroethylene (PTFE) with Carbon Fibers	Polytetrafluoroethylene (PTFE) with Carbon Fibers	Polytetrafluoroethylene (PTFE) with Carbon Fibers
Classification	Class II	Class II	Class II	Class II
Product Code	KKY	KKY	KKY	KKY
Intended Use	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.	Is designed individually for each patient to correct trauma and/or defects in mandibular, maxillofacial, or craniofacial bone	The augmentation or reconstruction of the craniomaxillofacial skeleton. Specific indications (SynPOR HD Ocular Spheres): * Occular reconstruction * Socket preservation Specific indications (SynPOR HD Facial Shapes): * Enhancement of the malar and chin * Correction of deficiencies of the malar and chin	Information not provided
Materials	OXPEKK® Polymer	Simplex P Bone Cement (PMMA)	Porous High Density Polyethylene (HDPE)	PMMA

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Characteristic	Subject Device (OPSFD)	Stryker® Patient Specific Polymer Implant (K103010)	Synthes SynPOR HD Porous Polyethylene (K111323)	Polyclinic Medical Center Hard Tissue Replacement (HTR) Patient Matched Implant (K924935)
Dimensional Specifications	Custom sized to each patient using CT data	Custom sized to each patient using CT data	Information not provided	Information not provided
Biocompatibility	ISO 10993-3, 5, 6, 10, 11, and 18 compliant	Information not provided	Information not provided	Information not provided
Endotoxin	USP 85 & AAMI ST72: <2.15 EU/device (CSF contact)	AAMI ST72 LAL	Information not provided	Information not provided
Porous	No	Yes	Yes	Information not provided
Fixation	Plate and screw systems	Plate and screw systems	Information not provided	Information not provided
Curing Required	No	Yes	Information not provided	Information not provided
Sterilization	Non-sterile	Sterilized by gamma radiation	Sterilized, method not provided	Information not provided
Packaging Validation	ISTA 2A compliant	Sterile packaging validation	Information not provided	Information not provided

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 28, 2014

Oxford Performance Materials Incorporated
Ms. Leigh Ayres
Director of Scientific Regulatory Affairs
P.O. Box 585
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Re: K133809
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 26, 2014
Received: June 30, 2014

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 [redacted] se -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

4 - OPSFD Indications for Use Statement

510(k) Number (if known): K133809

Device Name: OsteoFab™ Patient Specific Facial Device

Indications for Use:

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.

Prescription Use _√_ **(Part 29 CFR 801 Subpart D)**	**AND/OR**	**Over-The-Counter Use (29 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S

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