Matrix Surgical Holdings, LLC/Matrix Surgical USA
John O'Shaughnessy
President/CEO

October 11, 2018

4025 Welcome All Road - Suite 120
Atlanta, GA 30349

Re: K180249
Trade/Device Name: OmniPore® DUROMAX® Surgical Implants
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: October 10, 2018
Received: September 13, 2018

Dear Julie Stephens:

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,

Mary S. Runner -S3

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K180249

Device Name
OmniPore® DUROMAX® Surgical Implants

Indications for Use *(Describe)*
OmniPore® DUROMAX® Surgical Implants are intended for non-weight bearing applications of maxillofacial and orbital reconstruction, cosmetic surgery and repair of maxillofacial and orbital trauma.

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.

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"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

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By: Matrix Surgical Holdings, LLC dba Matrix Surgical USA
4025 Welcome All Road - Suite 120
Atlanta, GA 30349
Phone: (404) 869-3794

Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.
Phone: (678) 513-0693

Date Submitted: REVISED - October 10, 2018

Device Name and Classification:

Trade/Proprietary Name:	OmniPore® DUROMAX® Surgical Implants
Common Name:	Bone Plate
Classification Name:	Bone Plate
Regulation:	21 CFR 872.4760
Class:	II
Product Code:	JEY

Legally Marketed Predicate Devices:

Predicate: Synthes USA New Sterile Orbital Plates - 510(k) # K031761
Reference: OmniPore® Surgical Implants - 510(k) # K123908
Synthes [SynPOR] Porous Polyethylene Implants - 510(k) # K051879

Device Description:

The OmniPore DUROMAX Surgical Implants are an extension within the family of OmniPore Surgical Implants. OmniPore DUROMAX Surgical Implants include the addition of pure titanium within the porous high-density polyethylene. They are marketed as single use sterile implants with various sizes.

The material used for the OmniPore DUROMAX Surgical Implants is a porous high-density (HD) polyethylene. Polyethylene has a long history of use in surgical implantable products. The interconnecting open pore structure of the implants allow for tissue ingrowth. Both of the materials used to manufacture the OmniPore DUROMAX Surgical Implants, the porous HD polyethylene and pure titanium, have been utilized in reconstruction and soft tissue repair for many years. There is a long history of the use of porous polyethylene and titanium implants for enucleation and evisceration, as well as for reconstruction/cosmetic surgery and repair of the orbital skeletal framework, including orbital floors, walls, rims and roof, with a history of safety and performance. The interconnecting open pore structure of the OmniPore DUROMAX Surgical Implants allow for tissue ingrowth. Additionally, animal histology has shown fibrovascular ingrowth occurs into the open pore structure of porous surgical implants. The other advantage to the OmniPore DUROMAX Surgical Implants is that the titanium structure can be curved or rounded and will hold that shape in the internal orbital skeletal framework. The titanium material contained in OmniPore DUROMAX Surgical Implant is also radiopaque

510(k) Summary

on post-operative CT (computed tomography) scans. The implants are single use and provided sterile by ethylene oxide (EO) terminal sterilization.

Indications for Use:

OmniPore® DUROMAX® Surgical Implants are intended for non-weight bearing applications of maxillofacial and orbital reconstruction, cosmetic surgery and repair of maxillofacial and orbital trauma.

Comparison of Indications of Use to the Predicate Devices

Predicate Device 510(k) #: K031761	Reference Predicate Device 510(k) #: K123908	Reference Predicate Device 510(k) #: K051879
Synthes USA New / Sterile Orbital Plates	OmniPore® Surgical Implants	Synthes [SynPOR] Porous Polyethylene Implants
The Synthes Craniofacial Plates are intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	OmniPore Surgical Implants in block, sheet, and anatomical shapes are intended for non-weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. OmniPore Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.	Synthes Porous Polyethylene implants are intended for use in non-load bearing applications in craniofacial reconstruction, cosmetic surgery, and repair of craniofacial trauma.

The Indications for Use statement for OmniPore DUROMAX are equivalent to the predicate and reference predicate devices except for the difference of anatomical locations. This 510(k) submission includes the OmniPore DUROMAX Surgical Implants as a subset of the OmniPore Surgical Implants and are currently specific to “maxillofacial and orbital” anatomical locations and the Synthes 510(k)s, predicate and reference, included implants that were indicated for the cranial locations.

Technological Characteristics:

Comparison of Technological Characteristics to the Predicate Devices

The OmniPore DUROMAX Surgical Implants and the predicate devices have the same principles of operation to reconstruct the orbital floor and/or medial wall. The OmniPore DUROMAX Surgical Implants and the Synthes [SynPOR] Implants use the same materials, pure titanium embedded within porous high-density polyethylene. The Synthes Orbital plates include only pure titanium and the OmniPore Surgical Implants include only porous high-density polyethylene. The dimensions of the implants are similar. The proposed and predicate implants can all be trimmed and shaped to fit specific curvature and shapes of the individual patient’s anatomy. The proposed and predicate implants can all be used with the same fixation methods such as suture, wire, and/or fixation screws. Synthes recommends using the fixation screws they market and OmniPore recommends 1.5 mm titanium screws marketed by Biomet within their Facial and Neuro plate systems cleared under 510(k) # K121589 and # K121624. The proposed and predicate implants are permanent implants, provided sterile, single patient use only, and have non-pyrogenic claims. See Comparison Table on next page.

510(k) Summary

Comparison of Technological Characteristics to the Predicate Devices *(Continued)*

Proposed Device 510(k) #: K180249	Predicate Device 510(k) #: K031761	Reference Predicate Device 510(k) #: K123908	Reference Predicate Device 510(k) #: K051879
OmniPore DUROMAX Surgical Implants	Synthes USA New / Sterile Orbital Plates	OmniPore® Surgical Implants	Synthes [SynPOR] Porous Polyethylene Implants
Anatomical Locations: Implants for orbital or maxillofacial skeleton		Anatomical Locations: Implants for craniofacial skeleton which includes orbital and maxillofacial skeleton	
Materials: • HDPE • Pure titanium	Materials: • Pure titanium	Materials: • HDPE	Materials: • HDPE • Pure titanium
Dimensions: Titanium Material: Thickness - 0.2, 0.3 and 0.4 mm HDPE Material: Thickness - 0.8, 1.0, 1.5, and 1.6 mm; Height (over Titanium) - 35 to 38 mm Implant: Height - 43 to 50 mm; Width - 43 to 79 mm			
Fixation Methods: For use with sutures, K-wire, or 1.5 mm titanium screws	Fixation Methods: For use with 1.0 mm or 1.3 mm titanium screws	Fixation Methods: For use with sutures, K-wire, or surgical fixation screws	Fixation Methods: Compatible with 1.3 mm titanium screws

Summary of Testing:

The biocompatibility risk assessment was completed as directed by FDA guidance under ISO 10993-1 and Parts 5, 10, and 11 biocompatibility requirements. Cytotoxicity, Irritation, and Material-Mediated Pyrogenicity testing was completed to demonstrate and support justification that the known biocompatible materials, HDPE reviewed under OmniPore Surgical Implants 510(k) # 123908, and the addition of pure titanium per ASTM F67 and ISO 5832-2 standards maintained compliance through manufacturing and sterilization for the final implants. Compliance was justified for the OmniPore DUROMAX Surgical Implants against previous sterilization validation per ISO 11135 with Sterility Assurance Level (SAL) at 10^{-6} and EO Residuals requirements per ISO 10993-7 were met. The OmniPore DUROMAX Surgical Implants are non-pyrogenic per USP <161>, USP <85>, and USP <151>. Compliance was justified against previous five (5) year shelf life testing and previous mechanical testing specific to impact testing per ASTM D5420, purity testing per USP <661>, porosity and ingrowth testing per ASTM D4284 to the OmniPore Surgical Implants. Additional bench testing including bend, trim/cut, globe support, and fixation was completed to demonstrate that the addition of the titanium material supports substantial equivalence for the OmniPore DUROMAX Surgical Implants [proposed device] to the OmniPore Surgical Implants [reference predicate device].

Substantial Equivalence Conclusions:

The OmniPore DUROMAX Surgical Implants [proposed device] have the same principles of operation, an anatomical subpart of the general Indications for Use, and technological characteristics as the predicate devices.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalence under this notification is not intended to nor does it have any bearing whatsoever on the resolution of patent infringement or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.