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

May 14, 2014

Matrix Surgical Holdings, LLC/Matrix Surgical USA
% Regulatory Resources Group, Inc.
Julie Stephens
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K133046
Trade/Device Name: OmniPore® Customized Surgical Implants
Regulation Number: 21 CFR 878.3500
Regulatory Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: Class II
Product Code: KKY
Dated: April 08, 2014
Received: April 09, 2014

Dear Ms. 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. 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 Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: DMC
510(k) Staff
Division
D.O.

Indications for Use

510(k) Number (if known):

Device Name: OmniPore® Customized Surgical Implants

Indications for Use:

OmniPore® Customized Surgical Implants are intended for non-weight bearing applications of craniofacial reconstruction/ cosmetic surgery and repair of craniofacial trauma. OmniPore Customized Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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

Matrix Surgical USA
Traditional 510(k) - OmniPore® Customized Surgical Implants

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 / Matrix Surgical USA
575 14th Street, NW
Atlanta, GA 30318
Phone: (404) 862-3794
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Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.

Date Submitted: May 12, 2014 - Revised

Device Name and Classification:

Trade/Proprietary Name:	OmniPore® Customized Surgical Implants
Common Name:	Surgical Implants, Cranial and Facial
Classification Name:	Polytetrafluoroethylene with carbon fibers composite implant material
Product Code:	KKY

Legally Marketed Predicate Device:

Matrix Surgical USA - OmniPore® Surgical Implants - 510(k) # K123908
POREX Surgical Inc. (now owned by Stryker® Craniomaxillofacial) - MEDPOR® Customized Surgical Implant - 510(k) # K083621

Device Description:

The OmniPore® Customized Surgical Implants are marketed as single patient use sterile implants that physicians request as customized surgical implants which use identical materials and manufacturing to the OmniPore® Surgical Implants but are made to a predetermined patient's measurements and size requirements. The applications include non-load bearing augmentation and/or reconstruction of the craniofacial skeleton. The OmniPore Customized Surgical Implants are created from the patient's CT imaging data provided from the physician. The OmniPore Customized Surgical Implants are manufactured from the same material, manufactured under the same processes, and packaged the same as the OmniPore Surgical Implants.

The raw material used for the OmniPore Customized Surgical Implants is high-density polyethylene resin which has a long history of use in surgical implantable products. The interconnecting open pore structure of the OmniPore Customized Surgical Implants allow for tissue in-growth. Additionally, animal histology has shown fibrovascular in-growth occurs into the open pore structure of OmniPore Customized Surgical Implants.

The implants are single use and provided sterile by ethylene oxide (EO) terminal sterilization.

Matrix Surgical USA
Traditional 510(k) - OmniPore® Customized Surgical Implants

510(k) SUMMARY

Indications for Use:

OmniPore® Customized Surgical Implants are intended for non-weight bearing applications of craniofacial reconstruction/ cosmetic surgery and repair of craniofacial trauma. OmniPore Customized Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.

Similarities and Differences to the Predicate Devices:

Similarities

The same raw materials, manufacturing processes, packaging materials, sterilization facilities, performance standards, and indications for use are used with the OmniPore Customized Surgical Implants as with the OmniPore Surgical Implants.

Differences

There are slight differences in the OmniPore Customized Surgical Implants when compared against the MEDPOR predicate specific to manufacturing and sterilization facility locations.

Summary of Testing:

The OmniPore® Customized Surgical Implant materials are equivalent materials as the previously cleared OmniPore Surgical Implant devices so the biocompatibility and sterilization validation to validate that they are sterile devices for implantation was justified from the predicate testing. The OmniPore Customized Surgical Implants are equivalent materials as the previously cleared OmniPore Surgical Implant devices so the mechanical testing specific to impact testing, purity testing per USP, and porosity testing was justified from the OmniPore Surgical Implant device testing. The software verification and validation testing documentation for the OmniPore Customized Surgical Implants was provided to justify equivalence against the MEDPOR® Customized Surgical Implant.

Substantial Equivalence Conclusions:

The OmniPore® Customized Surgical Implants have the same intended use and indications for use, and the same technological characteristics and principles of operation as the predicate devices. The minor differences do not raise any issues of safety or effectiveness. Testing results support the determination of substantial equivalence with the results demonstrating that the OmniPore Customized Surgical Implants have equivalent results as the predicate devices.