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

January 20, 2016

Poriferous LLC
Mr. Jerri L. Mann
Chief Regulatory Officer
535 Pine Road, Suite 206
Newnan, Georgia 30263

Re: K152463
Trade/Device Name: SU-POR Patient-Specific Surgical Implant
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin prosthesis
Regulatory Class: Class II
Product Code: FWP
Dated: December 15, 2015
Received: December 21, 2015

Dear Mr. Mann:

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)*
K152463

Device Name
SU-POR Patient-Specific Surgical Implant

Indications for Use *(Describe)*
SU-POR Patient-Specific Surgical Implant in Customized shapes to meet the needs of Individual patients are intended for non-weight-bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. SU-POR Patient-Specific Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillifacial skeleton.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

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

SUBMITTER

510(k) Owner: Poriferous, LLC
535 Pine Road, Suite 206
Newnan, Georgia 30263-7640
Phone: (770) 683-3855
Fax: (770) 683-7459

Submitter: Jerri L Mann
Chief Regulatory Officer
Poriferous, LLC

Date Prepared: July 6, 2015

DEVICE

510(k) Number:	
Trade Name:	SU-POR Patient-Specific Surgical Implant
Common Name:	Prosthesis, chin, internal
Classification Name:	Chin prosthesis (21CFR 878.3550)
Regulatory Class:	Class II
Product Code:	FWP

PREDICATE DEVICES

Stryker CMF MEDPOR® Customized Implant - K143173
SU-POR Surgical Implants - K140437

DEVICE DESCRIPTION

The SU-POR Patient-Specific Surgical Implant is provided as a kit of two identical implants, one of which serves as a back-up implant. The SU-POR Patient-Specific Surgical Implant also provides the surgeon an option of a non-sterile non-implantable template made of the same high-density porous polyethylene to be utilized by the surgeon to assist in modifying the implant prior to placement. The SU-POR Patient-Specific Surgical Implant is manufactured from high-density porous polyethylene to fit the individual needs of a patient based on design input identified by the surgeon. The interconnecting porous structure of the material

allows for host tissue ingrowth. The SU-POR Patient-Specific Surgical Implant may be fixed into place using surgical plates and screws. The SU-POR Patient-Specific Surgical Implant is provided as a single-use sterile device.

INDICATIONS FOR USE

SU-POR Patient-Specific Surgical Implants in customized shapes to meet the needs of individual patients are intended for non-weight-bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. SU-POR Patient-Specific Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillifacial skeleton.

TECHNOLOGICAL AND OPERATIONAL CHARACTERISTICS

SU-POR Patient-Specific Surgical Implants are developed utilizing individual patient data provided by the surgeon via various means including CT scan data, a physical model, drawing, or other dimension and design information. A member of Poriferous' engineering team works one-on-one with the surgeon to create a design to meet the individual needs of a specific patient.

SIMILARITIES AND DIFFERENCES TO PREDICATE DEVICES

The following table provides an overview comparison of SU-POR Patient-Specific Implants to Stryker CMF MEDPOR® Customized Implants and SU-POR Surgical Implants:

	PROPOSED DEVICE	**PREDICATE # 1**	**PREDICATE # 2**
DEVICE NAME	SU-POR Patient-Specific Surgical Implant	SU-POR Surgical Implants	Stryker CMF MEDPOR® Customized Implants
510(k) NUMBER		K140437	K143173
MATERIAL	Porous high-density polyethylene (HDPE)	Porous high-density polyethylene (HDPE)	Porous high-density polyethylene (HDPE)
DESIGN	Patient-specific shapes based on precise design dimensions indicated by the surgeon via various	Pre-formed shapes, including sheets, blocks, spheres, and anatomical shapes	Specific reconstruction boundaries indicated by the surgeon vial submission of CT scans

	methods including CT scan data, a physical model, drawing or other dimension and design information		
STERILITY	Sterile	Sterile	Sterile
STERILIZATION METHOD	EtO	EtO	EtO
PACKAGING	Double Tyvek Pouch	Double Tyvek Pouch	Double Tyvek Pouch
BICOMPATIBLE	Yes	Yes	Yes
REUSABLE	No	No	No

PERFORMANCE DATA

SU-POR Patient-Specific Surgical Implant designs are created from information provided by the surgeon that is individualized for a specific patient. The design is verified and validated according to Poriferous' procedures for product design and development.

Biocompatibility Testing

There is no change in the material, duration, or location of contact or sterilization method from the cleared predicate SU-POR Surgical Implants - K140437. Therefore, biocompatibility was not required as a basis for substantial equivalence.

Performance Bench Testing

There is no functionality or performance change in comparison specifically to the cleared predicate SU-POR Surgical Implants - K140437. Additional bench testing is not required as a basis of substantial equivalence.

Software Verification and Validation Testing

The SU-POR Patient-Specific Implant does not directly contain software or have an electronic user interface. Software is used only in the design process for SU-POR Patient-Specific Surgical Implants. The manufacturing process does not incorporate the use of software. The same internal control systems in place for the cleared predicate SU-POR Surgical Implants - K140437 remain the same.

Animal Testing

Animal testing was conducted by Poriferous for the cleared predicate SU-POR Surgical Implants -K140437. There is no additional required animal testing as a basis for substantial equivalence.

Clinical Testing

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

Conclusions

Based on the historical data and the information provided in this submission, SU-POR Patient-Specific Surgical Implants will perform when used as intended. The comparison of SU-POR Patient-Specific Surgical Implants to SU-POR Surgical Implants and Stryker CMF MEDPOR Customized Implants, based on the requirements of 21 CFR 807.87 and the information provided herein, demonstrates substantial equivalence and does not raise any new issues of safety or effectiveness.