SYNTHES®

K140462

Special 510(k) Summary

JUN 13 2014

Date Prepared February 20, 2014

Submitter Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
United States of America

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Device Name MatrixNEURO Preformed Mesh
(part of the MatrixNEURO Cranial Plating System)

Device Classification Information

Product Code	Device Name	Device Class	Regulation Number	Regulation Description
GWO	Plate, Cranioplasty, Preformed, Alterable	2	882.5320	Preformed alterable cranioplasty plate

Predicate Devices

Synthes MatrixNEURO Cranial Plating System (K123723)

Indications for Use

MatrixNEURO Preformed Mesh is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

Device Description

The MatrixNEURO Cranial Plating System consists of bone fixation implants offered in a variety of shapes and sizes to meet the anatomical needs of the patient.

The proposed MatrixNEURO Preformed Meshes are precontoured to cover common cranial defects manufactured from grade 2 titanium that are designed for use with MatrixNEURO Cranial Plating System screws. The Preformed Meshes are offered sterile packed and are intended for single use only.

Comparison to Predicate Devices

Indications
The indications for proposed preformed meshes are identical to the predicate device.

Technological similarities between the predicate MatrixNEURO Reconstruction Mesh and the proposed MatrixNEURO Preformed Mesh:

- Same principles of operation – metallic implants for the fixation of bone.
- Same thickness as the predicate.
- Same mesh pattern (hourglass) as the predicate.
- Same bar width as the predicate.
- Same screw recess type (single-sided) as the predicate
- Same screw recess inner and outer diameter as the predicate and therefore compatible with same screws.
- Same strength-based color coding gradient as the predicate.
- Same material as the predicate.
- Both the proposed device and the predicate are provided sterile-packed.

Technological differences between the predicate MatrixNEURO Reconstruction Mesh and the proposed MatrixNEURO Preformed Mesh:

- The proposed devices are precontoured to cover common cranial defects and may be further contoured by the surgeon as necessary to fit the needs of each patient. The predicate device is provided flat and may be contoured by the surgeon as necessary to fit the needs of each patient.

Non-clinical performance data

Non-clinical testing and analyses comparing the proposed devices to the predicate include:

- Load at 2 mm of displacement
- Max Load between 0 and 2 mm displacement
- Stiffness at 2 mm of displacement

The non-clinical performance data demonstrate that the mechanical performance of the proposed Synthes MatrixNEURO Preformed Mesh is comparable to that of the predicate.

Clinical performance data

Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence

The proposed devices have the same intended use as the predicate devices. The non-clinical performance data discussed in this submission demonstrate that the proposed devices are as safe, as effective, and perform as well as or better than the predicate devices. It is concluded that the information included in this submission supports substantial equivalence.

(end of summary)

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

June 13, 2014

Synthes (USA) Products, LLC
Mr. Alan Haley
Senior Regulatory Affairs Specialist
1301 Goshen Pkwy.
West Chester, PA 19380

Re: K140462
Trade/Device Name: MatrixNEURO Preformed Mesh
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: May 5, 2014
Received: May 16, 2014

Dear Mr. Haley:

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 Small Manufacturers, International and Consumer Assistance 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" (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 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 Small Manufacturers, International and Consumer Assistance 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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 on last page.

510(k) Number *(if known)*
K140462

Device Name
MatrixNEURO Preformed Mesh (part of the MatrixNEURO Cranial Plating System)

Indications for Use *(Describe)*
MatrixNEURO Preformed Mesh is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

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)*

Carlos L. Pena -S

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