K133723

SYNTHES®

510(k) Summary

Date Prepared September 3, 2013

Submitter
Synthes (USA)
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United States of America

Contact
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Device Name Synthes MatrixNEURO Cranial Plating System

Device Class 2

Primary Product Code / Regulation Number

GWO / 21 CFR 882.5320

SEP 0 5 2013

Secondary Product Codes / Regulation Numbers

GXR / 21 CFR 882.5250

Predicate Devices

- Synthes Neuro Plate and Screw System (K042365)
- Synthes Low Profile Contourable Mesh Plates (K033160)
- Synthes Low Profile Neuro Plate and Screw System (K031807)
- Synthes Low Profile Neuro Plate and Screw System (K022012)

Indications for Use

The Synthes MatrixNEURO Cranial Plating System is intended for use in fixation of the cranial bones in procedures such as reconstruction, fracture repair, craniotomies, and osteotomies.

Device Description

The Synthes 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 reconstruction meshes are manufactured from titanium, are designed for use with Synthes MatrixNEURO Cranial Plating System screws, are offered sterile, and are intended for single use only.

The screws are manufactured from titanium alloy, are designed for use with Synthes MatrixNEURO plates, burr hole covers, and meshes, may be offered sterile or non-sterile, and are intended for single use only.

Comparison to Predicate Devices

Indications
The predicate devices are indicated for use in a range of anatomic areas (midface, craniofacial skeleton, maxilla, chin) for a variety of surgical applications (craniofacial surgery, reconstructive procedures, selective orthognathic surgery). The Indications for Use statement of the Synthes MatrixNEURO Cranial Plating System falls within the scope of the broader Indications statements of the predicate devices. The differences in the Indications statement for the proposed device in comparison to the predicates do not constitute a new intended use.

Technological Similarities (Reconstruction Meshes)
- Same principles of operation – metallic implants for the fixation of bone.
- Similar sizes and shapes compared to the predicates.
- Same thickness as the Low Profile Contourable Mesh Plate predicate.
- Same mesh pattern – hourglass cut-outs – to allow for similar intraoperative contourability.
- Same screw recess inner diameter as the predicate Synthes Neuro Plate and Screw System, and therefore compatible with same screws.
- Same strength-based color coding gradient as the predicate Synthes Neuro Plate and Screw System mesh.
- Same material as the predicates.
- The proposed reconstruction meshes are offered sterile. The meshes in the predicate Synthes Neuro Plate and Screw System are offered sterile and non-sterile.

Technological Differences (Reconstruction Meshes)
- The bar width and screw recess outer diameter dimensions of the proposed devices are greater than those of the predicates.
- The proposed Reconstruction Meshes feature a single-sided screw recess; the predicate devices feature double-sided screw recesses.

Technological Similarities (Screws)
- Same principles of operation – metallic implants for the fixation of bone.
- Similar lengths as the predicates.
- Same solid shaft as the Low Profile Neuro System predicates.
- Similar drive recess to the Low Profile Neuro System predicates.
- Similar type of tips on standard screw as the predicates.
- Same type of tip on emergency screw as the predicates.
- Same thread pitch as the Synthes Neuro Plate and Screw System predicate.
- Same material as the predicates.
- The proposed screws are offered sterile and non-sterile. The screws in the predicate Synthes Neuro Plate and Screw System are offered sterile and non-sterile.

Technological Differences (Screws)
- The major diameter of the standard screw is slightly smaller than the Low Profile Neuro System predicates.

Non-clinical performance data

Non-clinical performance data compared the proposed devices to the predicates:

- cross-sectional area
- section modulus
- peak load at 2 mm of displacement
- stiffness at 2 mm of displacement
- insertion torque
- failure torque
- insertion factor of safety
- pullout load

The non-clinical performance data demonstrate that the mechanical performance of the proposed Synthes MatrixNEURO reconstruction meshes and screws is comparable to that of the predicates.

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 included 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

September 5, 2013

Synthes (USA)
c/o Alan T. Haley
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, PA 19380

Re: K123723
Trade/Device Name: Synthes MatrixNEURO Cranial Plating System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, GXR
Dated: August 5, 2013
Received: August 6, 2013

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" (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 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: **K123723**

Device Name:

Synthes MatrixNEURO Cranial Plating System

Indications For Use:

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

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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