

3.0 510(k) Summary

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Sponsor:

Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380

Contact: Andrea M. Tasker
Regulatory Affairs Manager
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DEC 18 2007

Device Name:

Synthes (USA) 2.0mm Titanium T-Plate

Classification:

Class II
21 CFR § 882.5320
Common Name: Preformed alterable cranioplasty plate
Product Code: GWO

Predicate Device:

Bioplate Rigid Bone Plating System
Synthes Titanium Contourable Mesh Plates
Synthes Matrix Mandible Reconstruction Plate
Synthes Occipital-Cervical Plate

Device Description:

The Synthes (USA) 2.0mm Titanium T-Plate is a T-shaped plate configuration to be used with the Synthes 2.0mm screws. The plates are manufactured in titanium and are intended for single use only.

Intended Use:

The Synthes (USA) 2.0mm Titanium T-Plate is intended for use in the reconstruction of the cranium (skull) following surgical decompression procedures of the posterior fossa or transcervical skull based approach, with or without duraplasty, including procedures to treat Chiari Type I Malformation. The plate design is also intended for use in non-load bearing fixation, including cranial bone fixation. The device is intended for single use only.

**Substantial
Equivalence:**

Documentation is provided which demonstrates that the Synthes (USA) 2.0mm Titanium T-Plate is substantially equivalent to other legally marketed devices such as the plates in the Bioplate Rigid Bone Plating System, the Synthes Titanium Contourable Mesh Plates and the Synthes Matrix Mandible Reconstruction Plate.



DEC 18 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synthes (USA)
% Ms. Andrea Tasker
1301 Goshen Parkway
West Chester, PA 19380

Re: K072758
Trade/Device Name: Synthes (USA) 2.0mm Titanium T-Plate
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: II
Product Code: GWO
Dated: September 27, 2007
Received: September 28, 2007

Dear Ms. Tasker:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 - Ms. Andrea Tasker

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072758

Device Name: Synthes (USA) 2.0mm Titanium T-Plate

Indications: The Synthes (USA) 2.0mm Titanium T-Plate is intended for use in the reconstruction of the cranium (skull) following surgical decompression procedures of the posterior fossa or transcervical skull based approach, with or without duraplasty, including procedures to treat Chiari Type I Malformation. The plate design is also intended for use in non-load bearing fixation, including cranial bone fixation. The device is intended for single use only.

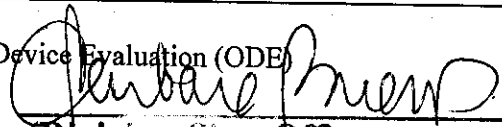
Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K072758