

K 031761

SEP - 3 2003

### 3.0 Summary of Safety and Effectiveness Information

**SPONSOR:** Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
(610) 647-9700  
Contact: Lisa M. Boyle

**DEVICE NAME:** Orbital Plates

**CLASSIFICATION:** Class II , 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories

**PREDICATE DEVICE:** Synthes Maxillofacial Titanium Micro Set  
Synthes Orbital Mesh Plates

**DEVICE DESCRIPTION:** The Synthes Orbital Plates come in a variety of shapes and sizes to meet the anatomical need of the patient. The plates are sterile / non-sterile and for single use only.

**INTENDED USE:** The Synthes Craniofacial Plates are intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

**MATERIAL:** CP Titanium

**SUBSTANTIAL EQUIVALENCE:** Documentation is provided which demonstrates that the Synthes Orbital Plates are substantially equivalent to other legally marketed Synthes devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Lisa Boyle  
Regulatory Associate  
Synthes (USA)  
1690 Russell Road  
Post Office Box 1766  
Paoli, Pennsylvania 19301

Re: K031761

Trade/Device Name: Synthes (USA) New / Sterile Orbital Plates  
Regulation Number: 21 CFR 872.4760  
Regulation Name: Bone Plate  
Regulatory Class: II  
Product Code: JEY  
Dated: June 5, 2003  
Received: June 6, 2003

Dear Ms. Boyle:

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.

Page 2 –Ms. Boyle

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.

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 Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "Susan Runner". The signature is written in a cursive style with a large, looped initial "S".

Susan Runner, DDS, MA  
Interim Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2.0 Indications for Use Statement

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510(k) Number (if known): K031761

Device Name: Synthes (USA) New / Sterile Orbital Plates

Indications:

The Synthes Craniofacial Plates are intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use   

Ken Malley for ODR  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K031761