OCT 2 9 2003

K033065

3. **510(k) Summary**

Sponsor:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
Company Contact:	Bonnie J. Smith
Device name:	2.0 mm Craniofacial Locking Plates
Classification:	Class II, §872.4760 – Plate, fixation, bone.
Intended use:	Synthes 2.0 mm Craniofacial Locking Plates are indicated for selective trauma of the midface and craniofacial skeleton; craniofacial surgery, reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.
Predicate device(s):	Synthes 2.0 mm Craniofacial Plates and Synthes 2.0 mm Mandible Locking Plates
Substantial Equivalence:	Documentation is provided which demonstrates that the Synthes 2.0 mm Craniofacial Locking Plates are substantially equivalent to the predicate devices.
Device description:	Synthes 2.0 mm Craniofacial Locking Plates provide a locking screw/plate interface. The plates contain threaded holes which allow the use of 2.0 mm Locking screws, 2.0 mm Cortex screws and 2.4 mm Emergency screws.
Material:	CP Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2003

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K033065
Trade/Device Name: 2.0 mm Craniofacial Locking Plates
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN, JEY
Dated: September 26, 2003
Received: September 29, 2003

Dear Ms. Smith:

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.

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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. **Indications for Use Statement**

510(k) Number (if known): K033065

Device Name: 2.0 mm Craniofacial Locking Plates

Indications for Use: Synthes 2.0 mm Craniofacial Locking Plates are indicated for 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 OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Rai Mulay for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices