K040272

FEB 2 3 2004

3.0 Summary of Safety and Effectiveness Information [510 Summary]

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Lisa M. Boyle
DEVICE NAME:	Craniofacial Plates
CLASSIFICATION:	Class II , 21 CFR 872.4760: Bone Plate
PREDICATE DEVICE:	Synthes Sagittal Split Plate
DEVICE DESCRIPTION:	The Synthes Double Adaption Plate can be cut or trimmed to the desired length to accommodate various fractures and meet the anatomical need of the patient. The plate has a low plate / screw head profile, uses 2.0 mm self-tapping or self-drilling bone screws and 2.4 mm emergency screws.
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.
SUBSTANTIAL EQUIVALENCE:	Documentation is provided which demonstrates that the Synthes CRANIOFACIAL Plates are substantially equivalent to other legally marketed Synthes devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2004

Ms. Lisa M. Boyle
Regulatory Associate
Synthes (USA), Incorporated
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K040272
Trade/Device Name: Synthes (USA) Craniofacial Plates
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: February 4, 2004
Received: February 5, 2004

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.

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-. 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

2.0 Indications for Use Statement

510(k) Number (if known): K040272

Device Name: Synthes (USA) Craniofacial 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.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K040272

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)