K974206

SYNTHES®

Summary of Safety and Effectiveness Information [510(k) Summary]

MAR 16 1998

SUBMITTER	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Sheri L. Musgnung
COMMON OR USUAL NAME	Plate, Cranioplasty, Preformed, Alterable; Fastener, Plate, Cranioplasty
DEVICE CLASSIFICATION	Class II, 21 CFR 882.5320 and 882.5360
PREDICATE DEVICE	Synthes Midfacial System (K953806)
DESCRIPTION	Synthes Cranial Spring Clip (CSC) is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure. The CSC has a T-profile, which consists of two semi-circular tabs, and two projections that are bent into springs to lodge in the diploe of the cranial bone surrounding the osteotomy. The two tabs are 0.2 mm thick and rest on the superior surfaces of the cranial flap and the surrounding cranial bone. The CSC has a low profile, is 11.5 mm in length, 9.0 mm in width, and is 4.2 mm in height (0.2 mm above the cranial surface). 1.5 mm Ti Alloy Bone Screws will be inserted laterally through the CSC and into the diploe. **The CSC is for single use only.**
INTENDED USE	Synthes CSC is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure. **The CSC is contraindicated in the following situations: in patients with a skull thickness less than 4 mm; or when the gap surrounding the bone flap is greater than 2 mm.** **The CSC is MRI compatible.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 1998

Ms. Sheri L. Musgnung
Regulatory Affairs Associate
Synthes USA
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K974206
Synthes (USA) Cranial Spring Clip
Regulatory Class: II
Product Codes: GWO and HBW
Dated: February 13, 1998
Received: February 17, 1998

Dear Ms. Musgnung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

Indications for Use Statement:

510(k) Number (if known): K974206

Device Name: Synthes (USA) Cranial Spring Clip (CSC)

Indications For Use:

Synthes CSC is intended to reattach a cranial bone flap to the surrounding Cranium after a craniotomy procedure.

The CSC is contraindicated in the following situations: in patients with a skull thickness less than 4 mm; or when the gap surrounding the bone flap is greater than 2 mm.

The CSC is MRI Compatible.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974206