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K022012

3. Summary of Safety and Effectiveness Information

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Matthew M. Hull (610) 647-9700 ext. 7191
Name of the Device	Synthes Low Profile Neuro System
Device Classification(s)	Class II, §872.4760 – Plate, Fixation, Bone Class II, §882.5250 – Burr Hole Cover Class II, §872.4880 – Screw, Fixation, Intraosseous
Substantial Equivalence	Documentation was provided which demonstrated the Synthes Low Profile Neuro System to be substantially equivalent to other legally marketed devices.
Device Description	The Synthes Low Profile Neuro System consists of titanium plates, meshes, and screws in a variety of shapes and sizes designed for various cranio-facial procedures.
Indications	The Synthes Low Profile Neuro System is 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	Plates & Meshes – Titanium Screws – Titanium Alloy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2002

Mr. Matthew Hull
Regulatory Affairs
SYNTHES (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301-1222

Re: K022012
Trade/Device Name: Synthes Low Profile Neuro System
Regulation Number: 872.4760, 872.4880 and 882.5250
Regulation Name: Bone Plate, Rotary Scaler and Burr Hole Cover
Regulatory Class: II
Product Code: JEY
Dated: October 7, 2002
Received: October 15, 2002

Dear Mr. Hull:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
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): K022012

Device Name: Synthes Low Profile Neuro System

Indications for Use:

The Synthes Low Profile Neuro System is 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 ✓ OR Over-The-Counter Use_
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K022012