SYNTHES®

K081747

SEP - 5 2008

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1301 Goshen parkway
West Chester, PA 19380
Contact: Andrea M. Tasker
(610) 719-6290

Device Name: Synthes (USA) Condylar Head Add-on-System - Modification

Classification: 21 CFR 872.3960: Mandibular condyle prosthesis

Predicate Devices: Synthes (USA) Condylar Head Add-on-System

Device Description: The Synthes Condylar Head Add-on System is an adjustable height add-on system for use with the 2.4 mm Locking Reconstruction Plate System and MatrixMANDIBLE Plate System. It consists of a condylar head, 2 screws, and one of four (4) fixation plates, each with a different screw hole spacing that determines the height of the condylar head.

Intended Use: Intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

Substantial Equivalence: Documentation is provided which demonstrates the Synthes (USA) Condylar Head Add-on-System - Modification to be substantially equivalent to other legally marketed devices such as:
Synthes (USA) Condylar Head Add-on-System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Ms. Andrea M. Tasker
Regulatory Affairs Specialist
Synthes (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K081747
Trade/Device Name: Synthes (USA) Condylar Head Add-on System
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: II
Product Code: NEI
Dated: June 16, 2008
Received: June 19, 2008

Dear Ms. Tasker:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

SYNTHES® K081747

2.0 Indications for Use

510(k) Number (if known): _____

Device Name: Synthes (USA) Condylar Head Add-on System

Indications for Use: Intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081747