SYNTHES®

K082649

APR 30 2009

3.0 **510(k) Summary**

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
Contact: Andrea M. Tasker
Phone: (610) 719-6920
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tasker.andrea@synthes.com

Device Name: Synthes 90 ° Screwdriver

Classification: Regulation Number: §872.4120
Device: drill, bone, powered
Regulation Description: Bone cutting instrument and accessories
Regulation Medical Specialty: Dental

Predicate Device: Synthes Electric Pen Drive System

Device Description: The Synthes 90 ° Screwdriver consists of a screwdriver handle, shaft, screw holder, screw holder insert and a variety of attachments such as drill bits and screwdriver blades for manual and powered right angled pre-drilling and insertion of screws.

Intended Use: The Synthes 90 ° Screwdriver is indicated for the manual and powered pre-drilling and insertion of bone fixation screws in oral/maxillofacial surgery.

Substantial Equivalence: Documentation provided supports substantial equivalence to other legally marketed devices such as the Synthes Electric Pen Drive System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 30 2009

Re: K082649
Trade/Device Name: Synthes 90 ° Screwdriver
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI, DZJ
Dated: April 17, 2009
Received: April 29, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SYNTHES®

1.0 Indications for Use

510(k) Number (if known): K082649

Device Name: Synthes 90 ° Screwdriver

Indications for Use:

The Synthes 90 ° Screwdriver is indicated for the manual and powered pre-drilling and insertion of bone fixation screws in oral/maxillofacial surgery.

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)

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

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