SYNTHES®

K093361

APR 14 2010

3.0 510(k) Summary

Sponsor:	Synthes (USA) 1301 Goshen Parkway West Chester, PA 19380 Phone: (610) 719-6538
Contact:	Jill R. Yelton, Regulatory Compliance Manager
Date of Preparation:	October 26, 2009
Device Name:	Synthes Air Pen Drive (APD) System
Classification:	21 CFR 872.4120: Drill, bone, powered 21 CFR 874.4250: Drill, surgical, ENT (Electric or Pneumatic 21 CFR 882.4310: Powered simple cranial drills, burrs, trephines, and accessories 21 CFR 882.4370: Pneumatic cranial drill motor
Predicate Device:	Synthes Electric Pen Drive (EPD) System (K043310) Midas Rex Legend System (K020069)
Device Description:	The Synthes Air Pen Drive (APD) System is a pneumatic powered system that consists of a Foot Pedal, Drive Unit, Hand Switch and Irrigation Control Unit that may be used with various commercially available attachments and cutting tools. The Drive Unit is pen-shaped and is connected to the Foot Pedal via a sterilizeable air hose. The rotation speed of the Drive Unit may be controlled from 0 to 60,000 rpm at 8 bar and from 0 to 80,000 at 12 bar via the Foot Pedal or the removable Hand Switch. Multiple attachments are available that have a quick-connect coupling to attach to the Drive Unit. The attachments accept various cutting tools including drill bits, burrs and saw blades.
Intended Use:	The Synthes Air Pen Drive (APD) is indicated for screw insertion, pin and wire placement, cutting of bone and metal, drilling, reaming, decorticating, shaping and smoothing of bones and teeth in a wide variety of surgical procedures, including general orthopedic trauma, foot, hand, maxillofacial, neurosurgical, oral, otolaryngological, reconstructive and spine surgery.
Substantial Equivalence:	Information presented supports substantial equivalence of the proposed device to the predicate device. The proposed device has the same indications for use, incorporates the same fundamental product technology and is composed of the same materials. Non-clinical testing was performed in accordance with current standards for functionality and reliability of the proposed device. Testing includes; duty cycle testing, wear and leak testing of couplings, valves hoses and seals, endurance testing of switches and valve control, noise testing and temperature testing. Additionally, engineering performance evaluation and analysis was performed comparing output torque and power of the proposed device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

APR 1 4 2010

Synthes (USA)
% Ms. Jill R. Yelton
Regulatory Compliance Manager
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K093361
Trade/Device Name: Synthes Air Pen Drive (APD) System
Regulation Number: 21 CFR 872.4120
Regulation Name:
Regulatory Class: Class II
Product Code: HBB
Dated: April 07, 2010
Received: April 08, 2010

Dear Ms. Yelton:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use

510(k) Number (if known): K093361

Device Name: Synthes Air Pen Drive (APD) System

Indications for Use:

The Synthes Air Pen Drive (APD) is indicated for screw insertion, pin and wire placement, cutting of bone and metal, drilling, reaming, decorticating, shaping and smoothing of bones and teeth in a wide variety of surgical procedures, including general orthopedic trauma, foot, hand, maxillofacial, neurosurgical, oral, otolaryngological, reconstructive and spine 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093361