SYNTHES®

MAY 28 1997

Attachment IX: Summary of Safety and Effectiveness Information K971544

Synthes (USA)
1690 Russell Road
Paoli, PA 19301

Contact: Sheri L. Musgnung
(610) 647-9700
April 1997

Synthes Compact Air Drive II (CAD II) is compared to Synthes Small Air Drill (SAD) and Synthes Universal Air Drill (UAD).

The Synthes CAD II is an air powered drill. It is used for drilling, reaming, sawing, burring, filing, and screwdriving functions. The CAD II accepts a variety of attachments and accessories.

The Synthes SAD and UAD is also used for drilling, reaming, burring, and screwdriving functions and accepts a variety of attachments and accessories.

Synthes CAD II has a 3.2 mm cannulated center to accept a variety of wires and pins. The other accessories include drill bits, flexible shafts, adapters, saw blades, air hoses, screwdriver shafts, burrs, files, and a cleaning brush. The drill features both forward and reverse rotation with a variable speed of 0 - 900 rpm; maximum torque of 4 Nm; air consumption of 250 liters/minute, and has an air control valve and latex free double air hose connection. The push button release allows for quick exchange of various attachments.

Based on the mechanical test results, Synthes CAD II is at least equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1997

Ms. Sheri L. Musgnung
Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
PO Box 1766
Paoli, Pennsylvania 19301

Re: K971544
Trade Name: Synthes (USA) Compact Air Drive II (CAD II)
Regulatory Class: I
Product Code: HWE
Dated: April 25, 1997
Received: April 28, 1997

Dear Ms. Musgnung:

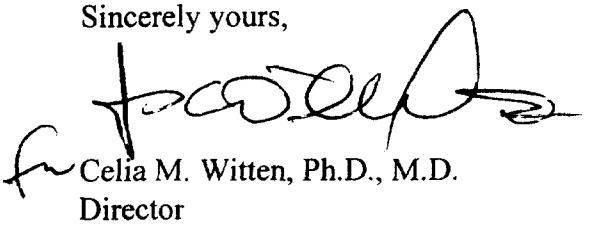
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4595. 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®

SYNTHES (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301
Telephone 610-647-9700

510(k) Number (if known): K971544

Device Name: Synthes (USA) Compact Air Drive II (CAD II)

Indications For Use:

Synthes CAD II is an air powered drill. It is used for drilling, reaming, sawing, burring, filing, and screwdriving functions.

(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 General Restorative Devices
510(k) Number K971544

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)