SYNTHES®

JUN 12 2000

K993335

Attachment VIII:

Summary of Safety and Effectiveness
[510(k) Summary]

SUBMITTER

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Sheri L. Musgnung

DEVICE NAME:

Synthes Reamer/Irrigator/Aspirator (RIA) System

COMMON OR USUAL NAME

Jet lavage;
Vacuum-powered body fluid suction apparatus;
Arthroscope

DEVICE CLASSIFICATION:

Class II, 21 CFR 880.5475; 880.6740; and 888.1100

PREDICATE DEVICE:

Synthes Inramedullary Reamers
Zimmer's Flexible Intramedullary Reamer
Davol's Pneumatic Arthroscopy Pulsed Irrigator System

DESCRIPTION:

The RIA System consists of two types of components; a series of disposable reamer assemblies and reusable drive shafts. The RIA is a device designed for expedited reaming of a medullary canal in preparation of internal fixation. The device includes a free rotating reamer head connected to the distal end of the manifold/tube assembly. The manifold allows both irrigation and aspiration during the reaming process. Irrigation is passed through the cannulation of the reamer and aspiration is drawn from the rear of the flutes in the reamer. The RIA coupled with the Drive Shaft serves as a flexible reaming device and is available in reaming diameters ranging from 9 mm to 24 mm and range in 200 mm to 550 mm in effective reaming lengths.

INTENDED USE:

Synthes RIA System is intended to clear the medullary canal of bone marrow and debris and to effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2000

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

Re: K993335
Trade Name: Synthes Reamer/IrrigatorAspirator (RIA) System
Regulatory Class: II
Product Code: HTO, HRX
Dated: May 1, 2000
Received: May 2, 2000

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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,

Donna R. Lochner for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K993335

Device Name: Synthes Reamer/Irrigator/Aspirator (RIA) System

Indications For Use:

Synthes RIA System is intended to clear the medullary canal of bone marrow and debris and to effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Donna R. Vochmer.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993335