SYNTHES®

JUL 28 2000

K994161

Attachment IX

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

SUBMITTER

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

Contact: Sheri L. Musgnung

DEVICE NAME:

Synthes Bioresorbable Suture Anchor

COMMON OR USUAL NAME

Fastener, Fixation, Biodegradable, Soft Tissue

DEVICE CLASSIFICATION:

Class II, CFR Unclassified

PREDICATE DEVICE:

Linvatec's Bio-Anchor Absorbable Suture Anchor
Mitek's Threaded Anchor (Fastin)
Mitek's GII Anchor

DESCRIPTION:

Synthes Bioresorbable Suture Anchors are injection molded from the poly(L/DL-lactide). Synthes Bioresorbable Suture Anchor is cylindrical in shape, ranges from 5.0 mm - 20.0 mm in length, has an outside diameter of 3.5 mm, and has a thread with metric profile. It is recommended to use a commercially available non-resorbable size #0, #1, or #2 USP suture in combination with this device. The Bioresorbable Suture Anchor has a drive mechanism which facilitates an interference fit of the device onto the suture anchor driver.

INTENDED USE:

Synthes Bioresorbable Suture Anchor is intended to repair ligamentous and tendinous defects in the shoulder, knee, foot, ankle, hand and wrist.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2000

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

Re: K994161
Trade Name: Synthes (USA) Bioresorbable Suture Anchor
Regulatory Class: II
Product Code: MAI
Dated: June 14, 2000
Received: June 15, 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 control provisions of the Act. The general control 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) 594-4659. 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. Bochner

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): K994161

Device Name: Synthes Bioresorbable Suture Anchor

Indications For Use:

Synthes Bioresorbable Suture Anchor is intended to repair ligamentous and tendinous defects in the shoulder, knee, foot, ankle, hand and wrist.

(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)

Diane R. Vochmer.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994161