SYNTHES®

K980944

APR 27 1998

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

1. **SPONSOR NAME AND ADDRESS**

Synthes (USA)
P.O. Box 1766
1690 Russell Road
Paoli, PA 19301
TEL: (610) 647-9700

Contact Person: Angela Silvestri, Regulatory Affairs Manager

2. **DEVICE NAME**

Synthes (USA) Schuhli Implant System

3. **CLASSIFICATION**

Synthes Schuhli Implant System has been classified as Class II devices, under 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories.

4. **INTENDED USE**

The Schuhli Implant System is intended for use with Synthes long bone and small bone plates and screws. The Schuhli Assembly locks the screw to the plate (independent of bone contact) and has the potential to decrease the possibility of the screw loosening and backing out of the bone. The devices are designed for, but are not limited to, use in osteoporotic bone for unicortical (of the far cortex) or bicortical fixation in cases of trauma, tumor, or infection, and as fixed angle devices (where the angle between two supporting members is fixed).

> WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

5. **DEVICE DESCRIPTION**

The Schuhli Implant System consists of a nut, a washer, and a temporary holding screw. The nut fits into the underside of the plate and has spikes which secure the nut to bone. The temporary holding screw is used to hold the Schuhli to the plate (before the screws are placed) while the surgeon obtains the correct placement of the plate. The washer fits into the plate's screw hole, accepting the head of a screw. The Schuhli Implant System is available in two sizes (4.5 mm and 3.5 mm); each size is available in either titanium or stainless steel, and is used with either titanium or stainless steel compression plates and screws, respectively. Synthes Schuhli Implant System will be provided to the user sterile. Gamma radiation will be used to sterilize the device.

6. **SUBSTANTIAL EQUIVALENCE**

Based on mechanical test results, the Schuhli Implant System is substantially equivalent to Synthes Dynamic Compression Plates and screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 1998

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes®
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K980944
Trade Name: Schuhli Implant System
Regulatory Class: II
Product Code: HTN
Dated: March 10, 1998
Received: March 12, 1998

Dear Ms. Silvestri:

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) 594-4659. 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,

for 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

510(k) Number (if known): K980944

Device Name. Synthes (USA) Schuhli Implant System

Indications for use:

Synthes Schuhli Implant System is intended for use with Synthes long bone and small bone plates and screws, to lock the screw to the plate in order to prevent the screw from loosening and backing out of the bone. Specifically, they are used in osteoporotic bone for unicortical (of the near cortex) or bicortical fixation in cases of trauma, tumor, or infection, and as fixed angle devices (where the angle between two supporting members is fixed).

(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 K980944

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