



K981757

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

SPONSOR

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

Contact: Angela Silvestri

**COMMON OR USUAL
NAME:**

Bone Plate and Bone Screw

**DEVICE
CLASSIFICATION**

Class II, 21 CFR 888.3030 and 888.3040

PREDICATE DEVICE:

Synthes LC-DHS

DESCRIPTION:

Synthes DHS Helix System is a plate and screw system. The DHS plate is a straight with an angled barrel portion that accepts a helix screw. The barrel angles are available in various degrees and the plates are available in multiple lengths. The plate accepts the DHS Helix Screw (lengths ranging from 75 mm to 130 mm) and 4.5 mm cortex screws.

INTENDED USE:

Synthes DHS Helix System is intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

MATERIAL:

Stainless Steel



JUL 17 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981757
Synthes (USA) DHS Helix System
Regulatory Class: II
Product Code: JDO
Dated: May 18, 1998
Received: May 19, 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.

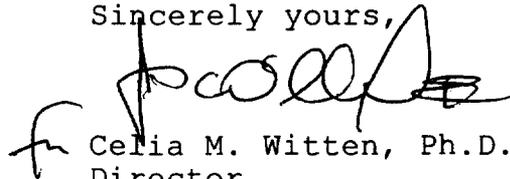
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

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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,


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



2.0 Indications for Use Statement

510(k) Number (if known): K981757

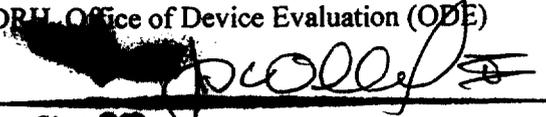
Device Name: Synthes (USA) DHS Helix System

Indications for use:

To treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

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

Concurrence of CDRL Office of Device Evaluation (ODE)



Sign-Off

General Restorative Devices

510(k) Number K981757

Prescription Use +
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

DHS Helix System
Synthes (USA)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____
CONFIDENTIAL