K000682

MAY - 1 2000

SYNTHES®

3.0 Summary of Safety and Effectiveness Information:

Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
CONTACT:	Angela Silvestri
DEVICE NAME::	Synthes Large Fragment Dynamic Compression Locking (DCL) System
DEVICE CLASSIFICATION:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories and 888.3040 Smooth/threaded metallic bone fixation fastener.
PREDICATE DEVICE:	Synthes Broad and Narrow Dynamic Compression Plates Synthes Anatomical Locking Plate System
DESCRIPTION OF DEVICE:	The Large Fragment DCL system consists of limited-contact profile plates in broad and narrow sizes, which include combination dynamic compression/locking screw holes. The plates accept 4.5 mm cortex, 6.5 mm cancellous, 4.5 mm cannulated, 7.0 mm cannulated, and 5.0 mm locking screws. This device is manufactured in either stainless steel or titanium.
INDICATIONS:	Synthes Large Fragment DCL is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

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4.0 Device Name:

Synthes Large Fragment Dynamic Compression Locking (DCL) System

5.0 Establishment Registration:

Synthes is registered with the Device Registration and Listing Branch (1719045) of the Food and Drug Administration (FDA). The devices subject to this premarket notification are manufactured by Synthes (USA), 1101 Synthes Avenue, Monument, CO 80132.

6.0 Classification Information:

The classification of the Synthes Large Fragment DCL System in our determination, Class II, as per Title 21 of the Code of Federal Regulations (21 CFR), sections 888.3030: Single/multiple component metallic bone fixation appliances and accessories and 888.3040 Smooth/threaded metallic bone fixation fastener.

7.0 Information Relating to Performance Standards and Special Controls:

Synthes Large Fragment DCL System is manufactured from 316L stainless steel, which adheres to American Society for Testing and Materials (ASTM) standard F 139; commercially pure titanium, which adheres to ASTM standard F67; and Titanium - 6% Aluminum – 7% Niobium (Ti-6Al-7Nb), which adheres to ASTM standard F 1295. Synthes is not aware of any performance standards or special controls established to date.

8.0 Sterilization Information:

Synthes will provide the device both sterile and non-sterile. Sterilization information on the sterile device can be found in Attachment I (a). Of course, non-sterile devices must be sterilized prior to use; moist heat sterilization is recommended using the parameters identified in Attachment I (b). These parameters have been validated using the Association for the Advancement of Medical Instrumentation (AAMI) guideline Steam Sterility Validation to provide a sterility assurance level (SAL) of 10^{-6}.

9.0 Description of the Device:

Synthes DCL System is a plate and screw system intended to treat fractures of various long bones. The primary feature of this system is limited-contact profile and the combination dynamic compression/locking screw holes. The standard screws facilitate reduction and create compression between the plate and bone, while the locking screws form a locked, fixed angle construct with the plate.

The DCL System includes both broad and narrow straight plates. The broad plates are 5.2 mm thick, 17.5 mm wide and are available in lengths ranging from 121 mm – 409 mm (6 – 22 screw holes). The narrow plates are 4.2 mm thick, 13.5 mm wide and are available in lengths ranging from 49 mm – 409 mm (2 – 22 screw holes). The screw holes are combined to allow placement of standard 4.5 mm cortex, 6.5 mm cancellous and 4.5 mm and 7.0 mm cannulated screws on one side of each hole, or 5.0 mm threaded conical, locking screws on the opposite side. The holes are

uniformly spaced along the length of the plate. The holes are oriented so that the compression component of the holes is always directed towards the middle of the plate.

The DCL System utilizes a locking feature that secures the screw to the plate, enabling unicortical or bicortical screw purchase. This feature consists of conical shaped, threaded locking screw holes in the plates that correspond with the conical- shaped, threaded head of the screw.

The 5.0 mm locking screws feature self-tapping tips, flat head profiles with rounded edges, and are available in lengths from 14mm to 90mm. The threads just below the head of each locking screw engages with the threaded side of the holes in the DCL plate. The engagement of these screws to the plate creates a locked, fixed angle construct.

Confidential engineering drawings may be found in Attachment II.

Synthes 4.5 mm cortex, 6.5 mm cancellous and 7.0 mm cannulated screws that are utilized with this system are commercially available devices.

The following Class I Exempt instruments are utilized with the DCL system: 4.3 mm drill bit and 4.3mm threaded drill guide.

10.0 Proposed Labels / Labeling:

Please see Attachment III for sterile and non-sterile device labeling.

11.0 Commercially Available Device Information:

The following Synthes devices are commercially available: Narrow and Broad Dynamic Compression Plates (pre-amendment status), Anatomical Locking Plate System (a.k.a. Synthes LISS) (K961413), 4.5 mm cortex and 6.5 mm cancellous (pre-amendment status), 4.5 mm Cannulated Screws (K963172) and 7.0 mm Cannulated Screws (K962011). Please see Attachment IV for information on these devices.

12.0 Comparison to Commercially Available Device:

A comparison of Synthes' DCL System to Synthes Broad and Narrow Dynamic Compression Plates and Synthes Anatomical Locking Plate System follows:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2000

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
SYNTHES (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301-1222

Re: K000682
Trade Name: Large Fragment Dynamic Compression Locking (DCL) System
Regulatory Class: II
Product Code: KTT
Dated: February 25, 2000
Received: February 29, 2000

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) 594-4595. 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. Bachner

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

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1.0 Indications for Use Statement

510(k) Number (if known): K000682

Device Name: Synthes (USA) Large Fragment Dynamic Compression Locking (DCL) System

Indications for use:

Synthes Large Fragment DCL is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Donna R. Vochmer
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000682