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K011335

## 3. Summary of Safety and Effectiveness Information

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|---|---|
| **Sponsor** | Synthes (USA)<br>1690 Russell Road<br>Paoli, PA 19301 |
| **Company Contact** | Matthew M. Hull<br>(610) 647-9700 ext. 7191 |
| **Name of the Device** | Synthes One-Third Tubular DCL Plate |
| **Regulation & Classification** | Class II, §888.3030 – Plate, Fixation, Bone (HRS) |
| **Predicate Device** | Synthes Third Tubular Plate (Pre-Amendment)<br>Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684) |
| **Device Description** | Synthes One-Third Tubular DCL Plate line extension is a threaded version of the currently marketed Synthes Third Tubular Plate. The threaded plates will accept locking screws and therefore can be included as part of the Small Fragment DCL System. The new plates have the same intended use as other plates in the system and there is no change in safety or efficacy. |
| **Intended Use** | Synthes Dynamic Compression Locking Plate System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone as a part of the Synthes Small Fragment DCL System. |
| **Technological Characteristics** | The Synthes One-Third Tubular Plate has the same technological characteristics as the predicate device/ system identified above. Both will be offered in the same materials and with the same sterility options. The only difference is that these new plates will have the locking threads and be offered as a part of the Synthes Small Fragment DCL System. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2001

Mr. Matthew M. Hull, RAC
Senior Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K011335
Trade Name: Synthes One-Third Tubular DCL Plate
Regulation Number: 21 CFR 888.3030
Regulatory Class: II
Product Code: HRS
Dated: April 30, 2001
Received: May 2, 2001

Dear Mr. Hull:

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 at (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, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**8. Indications for Use Statement**



510(k) Number (if known): K011335

Device Name: Synthes One-Third Tubular Plate

Indications/ Contraindications:

Synthes One-Third Tubular Plate is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone as a part of the Synthes Small Fragment DCL System.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011335