

3.0 510(k) SummaryPage 1 of 1

- Sponsor:** Synthes
Thomas N. Shea
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941
- Device Name:** Synthes 4.5mm VA-LCP Curved Condylar Plate System
- Classification:** Plates: Class II, §888.3030 – Single / multiple component metallic bone fixation appliance and accessories.

Screws: Class II, §888.3040 – Smooth or threaded metallic bone fixation fastener.
- Predicate Devices:** Synthes 4.5mm VA-LCP Curved Condylar Plates (K083025)
Synthes Locking Condylar Plate (LCP) System (K000066)
Synthes LCP Curved Plates (K041911)
Synthes SS/Ti LCP Distal Femur Plate (K062564)
Synthes 4.0/5.0mm Peri-Prosthetic Locking Screws (K041533)
- Device Description:** The Synthes 4.5mm VA-LCP Curved Condylar Plate System consists of anatomically contoured, stainless steel and titanium plates featuring variable angle locking and combi-holes designed to provide stable fixation of the distal femur.
- Intended Use:** The Synthes 4.5mm VA-LCP Curved Condylar Plate System is indicated for buttressing multifragmentary distal femur fractures including: supra-condylar; intra-articular and extra-articular condylar fractures, periprosthetic fractures, fractures in normal or osteopenic bone, nonunions and malunions.
- Substantial Equivalence:** Information presented supports substantial equivalence of the Synthes 4.5mm VA-LCP Curved Condylar Plate System to the predicate device K083025, Synthes 4.5mm VA-LCP Curved Condylar Plates. The proposed plates have the same indications for use, are similar in shape/design and incorporate the same fundamental technology. Mechanical testing was performed comparing the proposed plates to the predicate plates and the results support substantial equivalence.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Synthes USA
% Mr. Thomas N. Shea
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAR - 4 2011

Re: K110354

Trade/Device Name: Synthes 4.5mm VA-LCP Curved Condylar Plate System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation
appliance and accessories

Regulatory Class: Class II

Product Code: JDP, HRS, HWC

Dated: February 04, 2011

Received: February 09, 2011

Dear Mr. Shea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

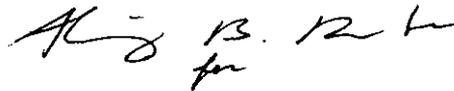
or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



2.0

Indications for Use

510(k) Number (if known): K110354

Device Name: Synthes 4.5mm VA-LCP Curved Condylar Plate System

Indications for Use:

The Synthes 4.5mm VA-LCP Curved Condylar Plate System is indicated for buttressing multifragmentary distal femur fractures including: supra-condylar; intra-articular and extra-articular condylar fractures, periprosthetic fractures, fractures in normal or osteopenic bone, nonunions and malunions.

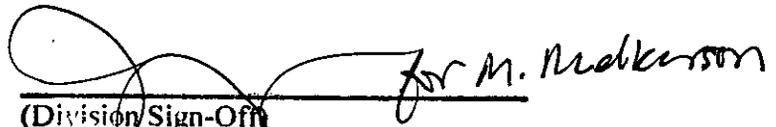
Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

 for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110354