SYNTHES®

K103243

3.0 510(k) Summary

Date Prepared: Jan 11, 2011

JAN 2 1 2011

Sponsor:
Synthes (USA)
Christopher Hack, Esq.
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

Device Name: 2.4mm VA-LCP Intercarpal Fusion System

Classification: Class II, §888.3030 – Single/multiple component metallic bone fixation appliances and accessories, HRS

Class II, §888.3040 – Smooth or threaded metallic bone fixation fastener, HWC

Predicate Device:
KMI – Wrist Fusion System (**K990094**)
KMI – Wrist Fusion System (**K991873**)
Acumed - Hub Cap Limited Wrist Fusion Plate (**K021321**)

Device Description: The 2.4mm VA-LCP Intercarpal Fusion System features low profile circular plates. The plates are available in two sizes: ø15mm (6 holes) and ø17mm (7 holes). The plates each feature variable angle locking technology. The plates also feature K-wire holes for positioning and temporary fixation.

Intended Use: The 2.4mm VA-LCP Intercarpal Fusion System is indicated for fusion of small bones of the hand including: hamate, capitate, lunate, and triquetrum, for the revision of failed partial wrist fusions, and is indicated for use in patients suffering pain and/or loss of function due to:

-Osteoarthritis
-Rheumatoid arthritis
-Post-traumatic or degenerative wrist arthritis
-Carpal instability

Substantial Equivalence: The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design. Engineering rationale demonstrates substantial equivalence of the subject components to the predicate device in regards to mechanical strength. In addition, the intended use, manufacturing methods, packaging, and sterilization of the predicate and subject components are identical.

The subject and predicate devices are made from stainless steel and titanium alloy (TAN). Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject 2.4mm VA-LCP Intercarpal Fusion System to the predicate devices. In support of this submission 1-point bending was performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Synthes (USA)
% Mr. Christopher Hack, Esq.
1301 Goshen Parkway
West Chester, PA 19380

JAN 21 2011

Re: K103243
Trade/Device Name: Synthes (USA) 2.4mm VA-LCP Intercarpal Fusion System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: October 29, 2010
Received: November 16, 2010

Dear Mr. Hack:

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" (21CFR 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,

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

Enclosure

SYNTHES®

2.0 Indications for Use

510(k) Number (if known): K103243

Device Name: Synthes (USA) 2.4mm VA-LCP Intercarpal Fusion System

Indications for Use:

The 2.4mm VA-LCP Intercarpal Fusion System is indicated for fusion of small bones of the hand including: hamate, capitate, lunate, and triquetrum, for the revision of failed partial wrist fusions, and is indicated for use in patients suffering pain and/or loss of function due to:

-Osteoarthritis
-Rheumatoid arthritis
-Post-traumatic or degenerative wrist arthritis
-Carpal instability

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (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. Mellerson

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

510(k) Number K103243