SYNTHES®

K102694

DEC 9 2010

4.0 510(k) Summary

Prepared: November 11, 2010

Purpose for Submission: To introduce a new plate system (K012694- 2.4mm Variable Angle LCP Dorsal Distal Radius System) into interstate commerce and to expand the indications of existing plate systems (K091644, K083694, K092556, K012114, K071184 and K031725) to include "skeletally mature adolescents and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius."

Bundled Plate Systems (for Pediatric Indication):

K091644 - 2.4mm LCP Volar Distal Radius Plates
K083694 - 2.4mm Variable Angle LCP Two-Column Volar Distal Radius Plates
K092556 - 2.4mm Variable Angle LCP Two-Column Narrow Volar Distal Radius Plates
K071184 - Variable Angle LCP Distal Radius System
K012114 – Synthes Locking Distal Radius Plating System
K031725 – Synthes Ti-15Mo Locking Distal Radius Plating System

Sponsor:

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

Device Name: 2.4mm Variable Angle LCP Dorsal Distal Radius 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

Predicate Device:

Synthes Locking Distal Radius Plating System – **(K012114)**
Synthes Distal Radius Plate System – **(K982732)**
Synthes Small Titanium Wrist Fusion Plate – **(K023879)**
Synthes Variable Angle Locking Compression Plate – **(K071184)**

Device Description: The 2.4mm Variable Angle LCP Distal Radius Plates are used with a range of 2.4 mm variable angle locking screws, 2.4 mm cortex screws, and 2.7 mm cortex screws. The dorsal plate has a pre-contoured design to fit along the dorsal radial column of the distal radius. These new plates incorporated variable angle locking technology. There are 6 different plate types and they are available in 316L stainless steel and CP -4 titanium. The plates are offered in 5 basic shapes: 2-hole L-plate, a 3-hole L-plate, straight (radial column) plates, oblique plates and T-plates. The L-plates, T-plates, and oblique plates come in 3- and 5-hole lengths. The straight (radial column) plates come in 5- and 6- hole lengths. The 2-Hole L-plate, a 3-hole L-plate, and oblique plates are also offered in left and right-angled configurations

Intended Use: The 2.4 mm LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis,

physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

Substantial Equivalence:

The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design. Mechanical testing demonstrates substantial equivalence of the subject components to the predicate devise 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 commercially pure titanium. Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject 2.4mm VA-LCP Dorsal Distal Radius System to the predicate devices.

Testing conducted to support the substantial equivalence of the 2.4mm VA- LCP Dorsal Distal Radius System was aimed to assess the fatigue strength of the subject device. Finite Element Analysis was used to determine the worst case construct and dynamic loading testing was used to confirm that the subject device construct is substantially equivalent to the predicate device construct.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Synthes (USA)
Christopher Hack, Esq.,
Regulatory Affairs Manager
1301 Goshen Parkway
West Chester, Pennsylvania 19380

DEC - 9 2010

Re: K102694
Trade/Device Name: Synthes 2.4mm Variable Angle LCP Dorsal Distal Radius Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 11, 2010
Received: November 15, 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): K102694

Device Name: Synthes (USA) 2.4mm Variable Angle LCP Dorsal Distal Radius Plates

Indications for Use:

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The 2.4 mm Variable Angle LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

Prescription Use X (Per 21 CFR 801.109) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

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

510(k) Number K102694

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Indications for Use

510(k) Number (if known): ~~K012694~~ K102694

Device Name: Synthes (USA) 2.4mm LCP Volar Distal Radius Plates

Indications for Use:

The 2.4 mm LCP Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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510(k) Number K102694

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Indications for Use

510(k) Number (if known): ~~K012694~~ K102694

Device Name: Synthes (USA) 2.4mm Variable Angle LCP Two-Column Volar Distal Radius Plates

Indications for Use:

The 2.4 mm Variable Angle LCP Two-Column Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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510(k) Number K102694

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Indications for Use

510(k) Number (if known): ~~K012694~~ K102694

Device Name: Synthes (USA) 2.4mm Variable Angle LCP Two-Column Narrow Volar Distal Radius Plates

Indications for Use:

The 2.4mm Variable Angle LCP Two-Column Narrow Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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510(k) Number K102694

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Indications for Use

510(k) Number (if known): ~~K021184~~ K102694

Device Name: Synthes (USA) Variable Angle LCP Distal Radius System

Indications for Use:

The Variable Angle LCP Distal Radius System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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510(k) Number K102694

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Indications for Use

510(k) Number (if known): ~~K012114~~ K102694

Device Name: Synthes (USA) Locking Distal Radius Plating System

Indications for Use:

The Synthes Locking Distal Radius Plating System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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510(k) Number K102694

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Indications for Use

510(k) Number (if known): ~~K031725~~ K102694

Device Name: Synthes (USA) Ti-15Mo Locking Distal Radius Plating System

Indications for Use:

The Ti-15Mo Locking Distal Radius Plating System Distal System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones in adults, skeletally mature adolescents, and the following adolescent distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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