510(k) Summary

Purpose of Submission: Is to modify the following previously cleared systems: Synthes (USA) Synthes Lateral Entry Femoral Nail (K040336) Synthes LISS System (Synthes Anatomic Locking Plate System) (K961413) Synthes (USA) Locking Condylar Plate System (K000066) Synthes (USA) LCP Curved Condylar Plates (K041911) Synthes LCP Distal Femur Plates (K062564) to introduce modified instruments, which are manual accessory instruments intended to facilitate compatibility with the Brainlab Trauma Navigation System.

Sponsor:
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Date: July 30, 2011

Contact:
Christopher Hack, Esq.
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941

Device Name: Synthes Brainlab Trauma Compatible Instruments

Classification:
Class II, §888.3020 – Intramedullary fixation rod.

Product Code: HSB (*Rod, Fixation, Intramedullary and Accessoies*).

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

Product Code: HRS (*Plate, Fixation, Bone*).

Product Code: KTT (*Appliance, Fixation, Nail/Blade Combination, Multiple Component*).

Predicate Devices:
Synthes (USA) Synthes Lateral Entry Femoral Nail (K040336)

Synthes LISS System (Synthes Anatomic Locking Plate System) (K961413)

Synthes (USA) Locking Condylar Plate System (K000066)

Synthes (USA) LCP Curved Condylar Plates (K041911)

Synthes LCP Distal Femur Plates (K062564)

Device Description: The Synthes (USA) Brainlab Compatible Instruments consist of manual insertion handles and aiming arms which are used to facilitate the surgical technique related to the Synthes Lateral Entry Femoral

Nail, LISS, LCP Distal Femur Plate, Locking Condylar Plate, and Curved Condylar Plate systems. The instruments primarily facilitate the manual insertion of the bone plate and intramedullary nail implants included in the predicate systems, but also include a design feature which allows attachment of system accessories to the Brainlab Trauma navigation system.

Intended Use:

Synthes Lateral Entry Femoral Nail System is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions. The Synthes Lateral Entry Femoral Nail System also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System

Synthes ALPS System is a plate and screw system intended to treat fractures of various long bones including radius, ulna, humerus, tibia, fibula, and femur. The Synthes ALPS is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System

Synthes LCP System is intended for buttressing multi-fragmentary distal femur fracture including supracondylar, intra-articular and extra-articular condylar fractures, fractures in normal or osteopenic bone, ad non –unions and malunions. The Synthes LCP is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System.

The Synthes Curved Broad Plates are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of per-prosthetic fractures, osteopenic bone and non-unions or malunions. The Synthes Curved Broad Plates is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System

The Synthes Curved Condylar Plates are intended for buttressing multi-fragmentary distal femur fractures, including: supracondylar, intra-articular and extra articular condylar fractures, peri-prosthetic fractures and fractures in normal or osteopenic bone, nonunions/malunions, and osteotomies of the femur. The Synthes Curved Condylar Plates is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System

Synthes LCP Distal Femur Plates are intended for buttressing multi-fragmentary distal femur fractures

including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fracture and fractures in normal osteopenic bone, non-unions and malunions, and osteotomies of the femur. The Synthes LCP Distal Femur Plate is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System.

Substantial Equivalence:

Information presented in this premarket notification supports that there are no effects of the described modification on the safety and effectiveness of the predicate Synthes Lateral Entry Femoral Nail (**K040336**), Synthes Distal Femur LISS (Synthes Anatomic Locked Plating System, **K961413**), Synthes Locking Condylar Plate System (**K000066**), Synthes LCP Curved Condylar Plate System (**K041911**), and Synthes LCP Distal Femur Plates (**K062564**). The modification does not affect the predicate system's indications for use, design of intramedullary implants, fundamental technology and or implant material composition.

Dimensional tolerance analyses and simulated use studies were conducted and the results support the conclusion that there are no effects of the modification subject to this premarket notification on the safety and effectiveness of the predicate systems.

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

NOV 2 8 2011

Re: K111891
Trade/Device Name: Synthes Brainlab Trauma Compatible Instruments
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HRS, KTT
Dated: October 27, 2011
Received: October 31, 2011

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.

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K111891 (pg. 1 of 5)

Device Name: Synthes (USA) Lateral Entry Femoral Nail System

INDICATIONS FOR USE:

Synthes Lateral Entry Femoral Nail System is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions. The Synthes Lateral Entry Femoral Nail System also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System

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)

Michael Owens for MKM

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

510(k) Number K111891

Indications for Use

510(k) Number (if known): K111891 (pg. 2 of 5)

Device Name: Synthes (USA) Anatomic Locking Plate System

INDICATIONS FOR USE:

Synthes ALPS System is a plate and screw system intended to treat fractures of various long bones including radius, ulna, humerus, tibia, fibula, and femur. The Synthes ALPS is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111891

Indications for Use

510(k) Number (if known): K111891 (pg. 3 of 5)

Device Name: Synthes (USA) Locking Condylar Plates

INDICATIONS FOR USE:

Synthes LCP System is intended for buttressing multi-fragmentary distal femur fracture including supracondylar, intra-articular and extra-articular condylar fractures, fractures in normal or osteopenic bone, and non – unions and malunions. The Synthes LCP is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System.

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

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and Restorative Devices

510(k) Number K111891

Indications for Use

510(k) Number (if known): K111891 (pg. 4 of 5)

Device Name: Synthes (USA) LCP Curved Plates

INDICATIONS FOR USE:

The Synthes Curved Broad Plates are intended for fixation of various long bone, such as the humerus, femur, and tibia. They are also for use in fixation of per-prosthetic fractures, osteopenic bone and non-unions or malunions. The Synthes Curved Broad Plates is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma navigation system

The Synthes Curved Condylar Plates are intended for buttressing multifragmentary distal femur fractures, including: supracondylar, intra-articular and extra articular condylar fractures, peri-prosthetic fractures and fractures in normal or osteopenic bone, nonunions/malunions, and osteotomies of the femur. The Synthes Curved Condylar Plates is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System

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

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and Restorative Devices

510(k) Number K111891

Indications for Use

510(k) Number (if known): K111891 (pg. 5 of 5)

Device Name: Synthes (USA) LCP Distal Femur Plate

INDICATIONS FOR USE:

Synthes LCP Distal Femur Plates are intended for buttressing multi-fragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fracture and fractures in normal osteopenic bone, non-unions and malunions, and osteotomies of the femur. The Synthes LCP Distal Femur Plate is also indicated for use with manual accessory instruments intended to be used with the Brainlab Trauma Navigation System

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 K111891