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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the CLAW® II Polyaxial Compression Plating System.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002
Date:	October 7, 2011
Contact Person:	Peggy S. Rivers Regulatory Affairs Specialist (901) 867-4759
(a)(2). Proprietary Name:	**CLAW® II Polyaxial Compression Plating System** **ORTHOLOC™ 3DSi Locking Screw**
Common Name:	Plate System and Locking Screws
Device Classification Regulation:	21 CFR 888.3030—Class II
Device Product Code & Panel:	HRS: Plate, Fixation Bone 87 orthopedics
(a)(3). Predicate Device:	K102352—EVOLVE® EPS ORTHOLOC™ System K051908— CHARLOTTE® CLAW® Plating System K080295— CHARLOTTE® CLAW® 3.5 Plating System

K093914— NEWDEAL® COMPRESSION PLATES
K091614—OSTEOMED FOOT PLATING SYSTEM
K101240—DEPUY ALPS SMALL BONE LOCKED PLATING SYSTEM
K083843—LOCKING ANATOMIC & COMPOSITE PLATING SYSTEM
K073624—MODULAR FOOT SYSTEM
K100618—MAXLOCK EXTREME® EXTREMITY PLATING SYSTEM

(a)(4). Device Description

The CLAW® II Polyaxial Compression Plating System consists of plates and screws of various anatomic configurations and lengths. All plates and screws are manufactured from implant grade stainless steel. The plates accept 2.7mm and 3.5mm ORTHOLOC™ 3DSi locking screws.

The ORTHOLOC™ 3DSi Locking Screws are made from implant grade stainless steel and are available with cortical and cancellous thread forms in multiple length and diameters.

The design features of the CLAW® II Polyaxial Compression Plating System and ORTHOLOC™ 3DSi Locking Screws are substantially equivalent to the design features of the predicate devices identified in this premarket notification.

(a)(5). Intended Use

Wright's CLAW® II Polyaxial Compression Plating System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocubid, Lapidus)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

(a)(6). Technological Characteristics Comparison

The technological characteristics of the CLAW® II Polyaxial Compression Plating System and ORTHOLOC™ 3DSi Locking Screws are substantially equivalent to technological characteristics of the predicates identified in this 510(k) submission.

The subject designs and indications are substantially equivalent to the predicates identified in this 510(k) submission. The subject screws and locking feature are substantially equivalent to the predicates identified in this premarket submission.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence is shown through worst-case plate analysis, plate mechanical testing, polyaxial performance testing, and descriptive information. The results of the test show that the subject CLAW® II Polyaxial Compression Plating System and ORTHOLOC™ 3DSi Locking Screws can be expected to perform at least as well as the legally marketed predicate identified in this 510(k) submission.

The safety and effectiveness of the CLAW® II Polyaxial Compression Plating System and ORTHOLOC™ 3DSi Locking Screws are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence - Conclusions

Substantial equivalence is shown through worst-case plate analysis, plate mechanical testing, polyaxial performance testing, and descriptive information. The subject CLAW® II Polyaxial Compression Plating System designs are similar to the previous CHARLOTTE® CLAW® 3.5 designs in basic plate form, size and hole placement. The subject designs and indications are substantially equivalent to the predicates identified in this 510(k) submission. The subject CLAW® II Polyaxial Compression Plating System locking holes contain the ORTHOLOC™ design feature which was 501(k) cleared with the ORTHOLOC™ EVOLVE® EPS System, 510(k) K102352. No new types of safety and effectiveness questions can be expected. From the evidence given in the Premarket Notification, the subject devices can be expected to perform at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

JAN 31 2012

Wright Medical Technology, Inc.
% Ms. Peggy S. Rivers
5677 Airline Road
Arlington, TN 38002

Re: K113014
Trade/Device Name: CLAW® II Polyaxial Compression Plating System
ORTHOLOC™ 3DSi Locking Screws
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: January 11, 2012
Received: January 13, 2012

Dear Ms. Rivers:

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

K113014

Indications for Use

510(k) Number (if known):

Device Name: CLAW® II Polyaxial Compression Plating System and ORTHOLOC™ 3DSi Locking Screw

Indications For Use:

The CLAW® II Polyaxial Compression Plating System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocubid, Lapidus)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K113014