K121425 1/3

OCT 1 2012

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 ORTHOLOC™ 3Di Ankle Fusion Plating System.

1. Submitted By:

Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Date: August 6, 2012

Contact Person:

Samir Ibrahim, PhD, RAC
Regulatory Affairs Specialist II
(901) 290-5909

2. Proprietary Name: ORTHOLOC™ 3Di Ankle Fusion Plating System and ORTHOLOC™ Bone Screws

Common Name:
Bone Plate System
Screw, Fixation, Bone

Classification Name and Reference:
21 CFR 888.3030 – Class II
21 CFR 888.3040 – Class II

Device Product Code, Device Panel:
HRS: Orthopedic
HWC: Orthopedic

3. Predicate Devices:

K110670 – PERI-LOC Ankle Fusion Bone Plates
K100176 – Ascension® Ankle Fusion Plate System
K090139 – Torrier® Stabilis™ Ankle Arthrodesis Plate System
K073375 – Integra® / Newdeal® Tibiazys™ System
K060473 – Newdeal® Advansys™ TTC Plate
K061940 – Synthes® LCP Ankle Arthrdesis Plates
K112772 – ORTHOLOC™ Bone Screws

4. Device Description

ORTHOLOC™ 3Di Ankle Fusion Plating System: The ORTHOLOC™ 3Di Ankle Fusion Plating System contains 22 plates belonging to 1 of 3 general categories based on the contouring of each plate and intended surgical approach. All plates feature poly-axial locking screw holes and one or two compression slots. The plates are made from titanium alloy conforming to ASTM F136 or ISO 5832-3 and accept 4.5mm and 5.5mm ORTHOLOC™ 3Di locking screws, 4.5mm and 5.5mm ORTHOLOC™ Fully Threaded Bone Screws, and 5.5mm ORTHOLOC™ Partially-Threaded Bone Screws. Washers of the same material are also available for use with the ORTHOLOC™ Bone Screws.

ORTHOLOC™ Bone Screws: ORTHOLOC™ Bone Screws are cancellous or cortical, partially or fully threaded non-locking screws offered in various diameters and lengths. All screws are manufactured from ASTM F136 or ISO 5832-3 titanium alloy and intended for single use only. These screws are intended to be used with the appropriately sized washers to prevent the screw head from breaking through the cortex of the bone by distributing the forces/loads over a large area.

5. Intended Use

ORTHOLOC™ 3Di Ankle Fusion Plating System: Wright's ORTHOLOC™ 3Di Ankle Fusion Plating System is intended to facilitate arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints and tibiocalcaneal arthrodeses, in conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.

ORTHOLOC™ Bone Screws: ORTHOLOC™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

6. Technological Characteristics Comparison

ORTHOLOC™ 3Di Ankle Fusion Plating System: Based on a technical feature comparison, the subject device was found to be similar to all predicate devices with regard to design and materials. The subject plates also have a polyaxial locking feature that offers locking up to 15° off-axis, similar to the design used in ORTHOLOC™ 3Di Ankle Plating System (K102429).

ORTHOLOC™ Bone Screws: Two larger screw sizes are being added to the ORTHOLOC™ Bone Screw system. They share similar head, neck, and thread designs as the smaller screws that are currently cleared under K112772. These implants are available in the following size ranges:

Device	Diameters (mm)	Lengths (mm)
Non-Locking Fully Threaded	4.5 – 5.5	15 – 65
Non-Locking Partially Threaded	5.5	55 – 100

7. Substantial Equivalence – Non-Clinical Evidence

The indication statements of both the subject and predicates devices convey the same intended use and literature was provided to support the safe and effective use of plate/screw systems for fusing the ankle. Performance testing supports the effectiveness of the polyaxial

locking feature, screw torque / pullout resistance, and stress response of the plates. The subject plate locking mechanism evaluated in this testing was found to be acceptable for off-axis mechanical screw locking up to 3x as compared to a non-locking screw. Torque and pullout testing was performed and the results exceeded the pre-determined acceptance criteria. Additionally through mechanical engineering analysis, the stress response of the worst-case plate was found to be similar to a predicate plate.

8. **Substantial Equivalence – Clinical Evidence**

N/A

9. **Substantial Equivalence – Conclusions**

The design characteristics and surgical approach of the subject system do not raise any new types of questions of safety or effectiveness. Performance testing supports the effectiveness of the polyaxial locking feature, screw insertion / pullout resistance, and stress response of the plates. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

OCT 1 2012

Wright Medical Technology, Inc.
% Samir Ibrahim, Ph.D.
5677 Airline Road
Arlington, TN 38002

Re: K121425
Trade/Device Name: ORTHOLOC 3Di Ankle Fusion Plating System and ORTHOLOC Bone 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: September 18, 2012
Received: September 19, 2012

Dear Dr. Ibrahim:

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

INDICATIONS FOR USE STATEMENT

510(k) Number: K121425

Device Name: ORTHOLOC™ 3Di Ankle Fusion Plating System and ORTHOLOC™ Bone Screws

Indications For Use:

Wright's ORTHOLOC™ 3Di Ankle Fusion Plating System is intended to facilitate arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints and tibiocalcaneal arthrodeses, in conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.

ORTHOLOC™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121425

Prescription Use √
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)