APR - 2 2012 K120802 (1/3)

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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 ORTHOLOC™ 3Di Locking Screws and ORTHOLOC™ Bone Screws.

A.1. Submitted By:

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

Date: March 15, 2012

Contact Person:

Sarah Holtgrewe
Regulatory Affairs Project Specialist
(901) 867-4476

A.2. Proprietary Name: **ORTHOLOC™ 3Di Locking Screws & ORTHOLOC™ Bone Screws**

Common Name: Locking Plate Screw & Bone Screw

Device Classification Regulation: 21 CFR 888.3040—Class II

Device Product Code & Panel:

HWC: Screw, Fixation Bone
HRS: Plate, Fixation, Bone
87 Orthopedics

A.3. Predicate Devices:

K102429—ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC™ Bone Screws
K112772—ORTHOLOC™ Bone Screws--Modification

A.4. Device Description

The ORTHOLOC™ 3Di Locking Screws subject to this premarket notification include the 2.7mm diameter--26, 28, and 30mm length locking screws. The ORTHOLOC™ Bone Screws subject to this premarket notification include the non-locking 2.7mm low profile bone screws. All screws are manufactured from titanium alloy and have a solid core. The implants are single use only devices.

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A.5. Intended Use

Ankle Plates:

Wright's ORTHOLOC™ Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolous
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avusion Fractures

ORTHOLOC™ 3D iLocking Screws:

The ORTHOLOC™ 3Di locking screws are intended for use with Wright's ORTHOLOC™ 3Di Plating Systems of the same base material.

ORTHOLOC™ Bone Screws:

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

Washer

Wright's washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

A.6. Technological Characteristics Comparison

The subject 2.7mm locking screws are identical to the predicate 2.7mm locking screws with the exception of screw length. The subject 2.7mm bone/non-locking screws have an identical low-profile head and neck as the predicate 3.5 mm low-profile non-locking bone screws and identical thread form as the predicate 2.7mm locking screw.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence is shown through comparison of design characteristics, materials information, worst-case analyses, and ultimate, insertion, and removal torque testing. The

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results show that the subject screws can be expected to perform at least as well as the legally marketed predicate screws.

B.2. Substantial Equivalence – Clinical Evidence

N/A—clinical evidence not required

B.3. Substantial Equivalence - Conclusions

Substantial equivalence is shown through design characteristics, materials information, worst-case analysis, and ultimate, insertion, and removal torque testing. The subject locking screws are identical in indication for use, and all dimensional characteristics except screw length. The subject bone screws have an identical low-profile head and neck as the predicate 3.5 mm low-profile non-locking bone screws and identical thread form as the predicate 2.7mm locking screws. 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

Public Health Service

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

Wright Medical Technology, Incorporated
% Ms. Sarah Holtgrewe
Regulatory Affairs Project Specialist
5677 Airline Road
Arlington, Tennessee 38002

APR - 2 2012

Re: K120802
Trade/Device Name: ORTHOLOC™ 3Di Locking Screws & ORTHOLOC™ Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 15, 2012
Received: March 16, 2012

Dear Ms. Holtgrewe:

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,

For Peter Pitts

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

Enclosure

K120802(1/2)

Indications for Use

510(k) Number (if known): K120802

Device Name: ORTHOLOC™ 3Di Locking Screws & ORTHOLOC™ Bone Screws

Indications For Use:

Wright's ORTHOLOC™ 3Di Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolous
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avusion Fractures

The ORTHOLOC™ 3Di locking screws are intended for use with Wright's ORTHOLOC™ 3Di Plating Systems of the same base material.

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.

Wright's washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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(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 K120802