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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

NOV 2 3 2010

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 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC™ Bone Screws.

A.1. Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002
Date:	August 13, 2010
Contact Person:	Megan McCagh, RAC Regulatory Affairs Specialist (901) 867-4120
A.2. Proprietary Name:	**ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC™ Bone Screws**
Common Name:	Bone Plate System
Device Classification Regulation:	21 CFR 888.3030—Class II 21 CFR 888.3040—Class II
Device Product Code & Panel:	HRS: Plate, Fixation Bone HWC: Screw, Fixation Bone 87 Orthopedics
A.3. Predicate Device:	K091243—ORTHOLOC™ Ankle Plating System K082320—Wright™ Compression Screws

A.4. Device Description

The ORTHOLOC™ 3Di Ankle Plating System contains 45 plates belonging to 1 of 2 general categories—distal tibia and fibula—based on the contouring of each plate. All plates feature poly-axial locking screw holes. Some plates have k-wire holes, compression slots, or syndesmosis slots. The plates are made from titanium alloy and accept 2.7mm and 3.5mm ORTHOLOC™ 3Di locking screws, 3.5mm and 4.0mm ORTHOLOC™ Bone Screws, and 4.0mm Wright™ Compression Screws (cleared under K082320, now branded DART-FIRE®). Washers are also available for use with the ORTHOLOC™ Bone Screws.

The design features of the ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC™ Bone Screws are substantially equivalent to the design features of the predicate ORTHOLOC™ APS and Wright™ Compression Screws.

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 ORTHOLOC™ 3Di Ankle Plating System and the legally marketed predicate ORTHOLOC™ APS have similar indications, utilize similar instrumentation, and are identical in material, anatomical design and selection. The subject ORTHOLOC™ 3Di Ankle Plates have been modified to reduce the excess material and accommodate surgeon feedback. ORTHOLOC™ bone screws are identical in indications for use, diameter, and material and are included in the size range of the legally marketed predicate, Wright™ Compression Screws. The subject screws differ in thread pitch and form, and driver type.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence is shown through worst-case plate analysis torque to failure, polyaxial performance, torisional, and pull out/pull through testing. The results of the test show that the subject ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC™ Bone Screws can be expected to perform at least as well as the legally marketed predicate ORTHOLOC™ APS and Wright Compression Screws.

The safety and effectiveness of the subject ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC™ Bone Screws is adequately supported by the substantial equivalence information, materials information, and comparison of design characteristics provided within the Premarket Notification.

B.2. Substantial Equivalence – Clinical Evidence

N/A

B.3. Substantial Equivalence - Conclusions

Substantial equivalence is shown through worst-case plate analysis and torque to failure, polyaxial performance, torisional, and pull out/pull through testing. The subject plates are identical to the predicate plates in material, anatomical design and selection, and thickness materials, and similar in indications, and instrumentation utilized. The subject plates have been modified to accept the modified predicate screws with a smaller distal pitch. The subject screws are identical in indication for use, diameter, size range and material to the predicate, and differ in thread pitch and form and driver type. 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, Inc.
% Ms. Megan McCagh, RAC
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

NOV 23 2010

Re: K102429
Trade/Device Name: ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC™ Bone Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and appliances
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 24, 2010
Received: August 25, 2010

Dear Ms. McCagh:

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

NOV 2 3 2010

510(k) Number (if known): K102429

Device Name: ORTHOLOC™ 3Di Ankle Plating System

Indications For Use:

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- Lateral Malleolar Fractures
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- Medial Malleolar Fractures
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- Distal Tibia Shaft Fractures
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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)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K102429