K110552 1/2

MAR 2 3 2011

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 VALOR® Ankle Fusion Nail System – Extended Screw Lengths.

A.1. Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002
Date:	February 25, 2010
Contact Person:	Ryan Bormann Regulatory Affairs Specialist (901) 867 - 4409
A.2. Proprietary Name:	**VALOR® Ankle Fusion Nail System – Extended Screw Lengths**
Common Name:	Ankle Fusion Nail
Device Classification Regulation:	21 CFR 888.3020--Class II
Device Product Code & Panel:	HSB Rod, Fixation, Intramedullary and Accessories 87 Orthopedics
A.3. Predicate Device:	VALOR® Ankle Fusion Nail System (K090857)

A.4. Device Description

The VALOR® Ankle Fusion Nail System – Extended Screw Lengths are a line extension to the existing VALOR® Ankle Fusion Nail System and will be offered in multiple lengths. The implants will be manufactured from titanium alloy.

The design features of the VALOR® Ankle Fusion Nail System – Extended Screw Lengths are substantially equivalent to the design features of other devices previously cleared for market.

A.5. Intended Use

The VALOR® Ankle Fusion Nail System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include Neuro-osteoarthropathy (Charcot's Foot), Avascular Necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, Osteoarthritis, Rheumatoid Arthritis, and Pseudoarthrosis.

A.6. Technological Characteristics Comparison

The subject VALOR® Ankle Fusion Nail System – Extended Screw Lengths and the legally marketed predicate VALOR® Ankle Fusion Nail System have the same indications, materials and design.

The VALOR® Ankle Fusion Nail System – Extended Screw Lengths differ from the legally marketed predicate VALOR® Ankle Fusion Nail System in overall length.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence was shown through fatigue testing. The results of the test show that the subject VALOR® Ankle Fusion Nail System – Extended Screw Lengths can be expected to perform at least as well as legally marketed predicate devices.

The safety and effectiveness of the VALOR® Ankle Fusion Nail System – Extended Screw Lengths 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 bench testing and design characteristics. The materials and indications are similar and 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

Wright Medical Technology, Inc.
% Mr. Ryan Bormann
5677 Airline Road
Arlington, TN 38002

MAR 2 3 2011

Re: K110552
Trade/Device Name: VALOR Ankle Fusion Nail System – Extended Screw Lengths
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: February 25, 2011
Received: February 28, 2011

Dear Mr. Bormann:

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 Pronovost MD
Deputy Director for Clinical Affairs

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): K110552

Device Name: VALOR® Ankle Fusion Nail System – Extended Screw Lengths

Indications For Use:

The VALOR® Ankle Fusion Nail System is intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection. These include Neuro-osteoarthropathy (Charcot's Foot), Avascular Necrosis of the talus, failed joint replacement, failed ankle fusion, distal tibia fracture non-unions, Osteoarthritis, Rheumatoid Arthritis, and Pseudoarthrosis.

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

for M. Mellerson

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

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