DEC 1 6 2011

K110360 1/2

Create Motion.™ WRIGHT.

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 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd. Arlington, TN 38002
Date:	December 12, 2011
Contact Person:	Sarah Holtgrewe Manager, Regulatory Affairs (901) 867-4476
Proprietary Name:	**PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides**
Common Name:	Alignment Guides
Classification Name and Reference:	21 CFR 888.3110--Ankle joint metal/polymer semi-constrained cemented prosthesis--Class II
Device Product Code and Panel Code:	Orthopedics/87/ HSN, OYK
Predicate Devices:	INBONE® Total Ankle Replacement (K051023)

DEVICE INFORMATION

A. DEVICE DESCRIPTION

PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides are patient-specific guides created to fit the contours of the patient's distal tibial and proximal talar anatomy. The guides are designed and manufactured from patient imaging data (CT), and are made from biocompatible nylon. The PROPHECY® Guides serve as an alternative to traditional alignment instrumentation used with Wright's INBONE® Total Ankle System, and thereby reduce the overall number of surgical steps required during total ankle arthroplasty. The guides serve to position and align the INBONE® implants in a comparable position to that attainable with traditional INBONE® instrumentation.

B. INTENDED USE

Wright's PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total ankle replacement components intra-operatively and in guiding the marking of bone before cutting. The PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides are intended for use with Wright's INBONE® Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides are intended for single use only.

C. PERFORMANCE DATA

The following performance data was used to support the safety and efficacy of the PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides:

- Repeatability testing across design engineers
- Guide placement repeatability testing
- Cadaver testing by end users analyzing placement location and orientation
- Detailed software descriptions and documentation

D. SUBSTANTIAL EQUIVALENCE INFORMATION

The main differences between the subject and predicate INBONE® system are in the patient-specific design and materials. The safety and efficacy of the PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this 510(k), including the following: a device design algorithm to illustrate the PROPHECY® INBONE® design goal, a comparison with traditional surgical technique, and user repeatability testing and cadaver testing to ensure repeatability of design algorithm execution.

headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone **www.wmt.com**

international subsidiaries
011.32.3.378.39.05 Belgium **905.826.1600** Canada **011.33.1.45.13.24.40** France **011.49.211.862.9990** Germany
011.39.0250.678.227 Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

DEC 16 2011

Wright Medical Technology, Inc.
% Ms. Sarah Holtgrewe
5677 Airline Road
Arlington, TN 38002

Re: K110360
Trade/Device Name: PROPHECY INBONE Pre-Operative Navigation Alignment Guides
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSN, OYK
Dated: September 29, 2011
Received: September 30, 2011

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 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): K110360

Device Name: PROPHECY® Pre-Operative Navigation Alignment Guides

Indications For Use:

Wright's PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total ankle replacement components intra-operatively and in guiding the marking of bone before cutting. The PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides are intended for use with Wright's INBONE® Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® INBONE® Pre-Operative Navigation Alignment Guides are intended for single use only.

Prescription Use xxx 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 K110360