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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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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 PROPHECY® INFINITY™ Preoperative Navigation Alignment Guides.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: (800) 238-7188 Fax: (901)867-4190
Date:	May 3, 2013
Contact Person:	Danielle Mueller *Project Manager | Regulatory Affairs*
Proprietary Name:	PROPHECY® INFINITY™ Preoperative 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
Subject Product Code and Panel Code:	Orthopedics/87/ HSN, OYK
Predicate Devices:	PROPHECY® INBONE® Preoperative Alignment Guides [K110360] INFINITY™ Total Ankle System [K123954]

DEVICE INFORMATION

A. Intended Use

Wright's PROPHECY® Preoperative 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® Preoperative Navigation Alignment Guides are intended for use with Wright's INBONE® and INFINITY™ 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® Preoperative Navigation Alignment Guides are intended for single use only.

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B. Device Description

PROPHECY® Preoperative 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® and INFINITY™ Total Ankle Systems, and thereby reduce the overall number of surgical steps required during total ankle arthroplasty. The guides serve to position and align the implants comparable to that attainable with traditional instrumentation.

The following evaluations were conducted to support the safety and efficacy of the PROPHECY® INFINITY™ guides:

- Guide design repeatability across design engineers
- Guide placement repeatability
- Cadaver evaluation by end users analyzing placement location and orientation
- Software validation

These evaluations concluded the subject alignment guides are substantially equivalent to the predicates.

C. Substantial Equivalence Information

The main difference between the subject and predicate PROPHECY® guides is the addition of use with the INFINITY™ Total Ankle System. The design features and materials of the subject devices are substantially equivalent to those of the predicates. The fundamental scientific technology has not changed relative to the predicate devices. The safety and efficacy of the PROPHECY® guides are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Wright Medical Technology, Incorporated
% Ms. Danielle Mueller
Project Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

July 5, 2013

Re: K131283
Trade/Device Name: PROPHECY® INFINITY™ Preoperative Navigation Alignment Guides
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN, OYK
Dated: May 3, 2013
Received: May 6, 2013

Dear Ms. Mueller:

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 contact 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. 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 -S

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K131283

Device Name: PROPHECY® INFINITY™ Preoperative Navigation Alignment Guides

Indications For Use:
Wright's PROPHECY® Preoperative Navigation Alignment Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The PROPHECY® Preoperative Navigation Alignment Guides are intended for use with Wright's INBONE® and INFINITY™ 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® Preoperative Navigation Alignment Guides are intended for single use only.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices