K100886 1/2

AUG 26 2010

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 INBONE™ II Total Ankle System..

A.1. Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002
Date:	March 18, 2010
Contact Person:	Kelsey Lee Regulatory Affairs Specialist I (901) 290-5909
A.2. Proprietary Name:	**INBONE™ II Total Ankle System**
Common Name:	Ankle Prosthesis
Device Classification Regulation:	21 CFR 888.3110--Class II
Device Product Code & Panel:	HSN: Ankle joint metal/polymer semi-constrained cemented prosthesis 87 Orthopedics
A.3. Predicate Device:	INBONE™ Total Ankle System (K051023)

A.4. Device Description

The INBONE™ II Total Ankle System consists of tibial trays, talar domes and tibial inserts. The tibial trays and talar domes have modular stem connections. The tibial trays are manufactured from titanium alloy; the talar domes are manufactured from cobalt-chrome; and the tibial inserts are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The INBONE™ II Total Ankle System is compatible with the predicate INBONE™ Total Ankle System components.

The INBONE™ II Total Ankle System is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

The design features of the INBONE™ II Total Ankle System are substantially equivalent to the design features of other devices previously cleared for market.

A.5. Intended Use

The INBONE™ Total Ankle is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

Indications for Use

The INBONE™ Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The INBONE™ Total Ankle is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

The indications are similar to the legally marketed predicate device.

A.6. Technological Characteristics Comparison

The INBONE™ II Total Ankle System and the legally marketed predicate INBONE™ Total Ankle System have similar indications, utilize the same instruments, and are manufactured out of the same materials. The INBONE™ II Total Ankle System is also compatible with components from the legally marketed predicate INBONE™ Total Ankle System.

The INBONE™ II Total Ankle System differs from the legally marketed predicate in articulating surface geometry and additional stability in the talar dome.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence was shown through stability and contact area testing. The results of the test show that the subject INBONE™ II Total Ankle System can be expected to perform at least as well as the legally marketed predicate INBONE™ Total Ankle.

The safety and effectiveness of the INBONE™ II Total Ankle System 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 stability testing and contact area testing. The materials are identical and the indications are similar and the subject and predicate differ in articulating surface geometry and additional talar dome stability, but 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 Technologies, Inc.
% Ms. Kelsey Lee
5677 Airline Road
Arlington, TN 38002

AUG 26 2010

Re: K100886
Trade/Device Name: INBONE II Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSN
Dated: August 16, 2010
Received: August 17, 2010

Dear Ms. Lee:

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,

Barbara Brehup 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

K100886

510(k) Number (if known): K100886

Device Name: INBONE™ II Total Ankle System

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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)

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

510(k) Number K100886