DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 10, 2016

Exactech Incorporated
Shing Jen Tai, Ph.D.
Senior Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K152217
Trade/Device Name: Exactech® Vantage™ Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: February 16, 2016
Received: February 17, 2016

Dear Dr. Jen Tai:

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 Parts 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 Industry and Consumer Education 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152217

Device Name

Exactech Vantage Total Ankle System

Indications for Use *(Describe)*

The Vantage™ Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. It is also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

The Vantage™ Total Ankle System is indicated for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Exactech® Vantage™ Total Ankle System
Traditional 510(k)

510(k) Summary

Company: Exactech®, Inc
2320 NW 66th Court
Gainesville, FL 32653

Date: March 4, 2016

Contact Person: Shing Jen Tai, PhD
Sr. Regulatory Affairs Specialist

Phone: (352) 327-4638
Fax: (352) 378-2617

Proprietary Name: Exactech® Vantage™ Total Ankle System

Common Name: Total Ankle Prosthesis

Classification Name: 21 CFR 888.3110, Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis

Class II

Product Code: HSN

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

- Salto Talaris™ Total Ankle Prosthesis (K090076) from Tornier
- INFINITY® Total Ankle System (K123954, and K140749 - line extension to devices cleared in K123954) from Wright Medical Technology, Inc.

Device Description

Exactech Vantage Total Ankle System is a fixed-bearing total ankle replacement device that is comprised of four sub-components, a tibial plate, a tibial insert, a locking component, and a highly polished talar component that are assembled to create the subject total ankle replacement system. The tibial plate is manufactured from titanium alloy (Ti-6Al-4V ELI) with commercially pure titanium coating on the bone-contacting surface. The tibial insert is made of ultra-high molecular weight polyethylene. The highly polished talar component is manufactured from cobalt-chromium alloy (Co-28Cr-6Mo) with commercially pure titanium coating on the bone-contacting surface. The locking component is made of titanium alloy (Ti-6Al-4V ELI). Each of the four sub-components is offered in multiple sizes to accommodate the various anatomical needs of a patient's ankle joint. With the exception of the locking component, all components are anatomically designed and offered in left and right implant components. The overall design goals of the Exactech Vantage Total Ankle System are to maximize bony support while allowing impingement-free range of motion, and provide anterior/posterior,

medial/lateral, and rotational stability when implanted in the resected/prepared distal tibia and proximal talus. Exactech Vantage Total Ankle System device is indicated for cemented use only.

The Exactech Vantage Total Ankle System is accompanied by a complete instrumentation set including trial and rasp/cutting block system to assist surgeons in implantation of the device.

Indications for Use
The Vantage™ Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. It is also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

The Vantage™ Total Ankle System is indicated for cemented use only.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following device use and characteristics:

- **Indications for Use.** The proposed Exactech Vantage Total Ankle System and the predicate devices have similar and comparable indications for use.
- **Materials/Surface Coatings.** The proposed Exactech Vantage Total Ankle System and the predicate devices are composed of same or similar, biocompatible substrate materials, and the same surface coatings for permanent implants.
- **Design Features.** The proposed Exactech Vantage Total Ankle System and the predicate devices share similar design features.
- **Dimensions.** The proposed Exactech Vantage Total Ankle System and the predicate devices are dimensionally comparable.
- **Sterilization.** The proposed Exactech Vantage Total Ankle System and the predicate devices are provided sterile for single use only.
- **Performance Requirements.** The proposed Exactech Vantage Total Ankle System and the predicate devices conform to recognized performance standards for total ankle joint replacement devices.

Non-Clinical Testing
The following sizing studies, mechanical testing, and modeling analyses were performed to demonstrate that the Exactech Vantage Total Ankle System performs as intended and is substantially equivalent to the identified predicate devices:

- Sizing Studies
- Locking integrity Testing
- Fatigue Analysis
- Wear Evaluation
- Contact Area/Contact Stress Study

- Constraint Evaluation
- Bone Stability Testing
- Range of Motion Study
- Finite Element Analysis

Substantial Equivalence Conclusion

Based on consideration of indications for use, technological characteristics, and results of combined mechanical testing, modeling analyses, and sizing studies described above, it was concluded that Exactech Vantage Total Ankle System demonstrates substantial equivalence to the referenced predicate devices.