



October 12, 2023

Exactech, Inc.
Pedro Ravelo
Regulatory Affairs Specialist
2320 NW 66th Ct.
Gainesville, Florida 32653

Re: K230717

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: September 13, 2023
Received: September 13, 2023

Dear Pedro Ravelo:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -S

Lixin Liu, Ph.D

Assistant Director

DHT6A: Division of Joint Arthroplasty Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K230717

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.

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**Exactech® Vantage® Total Ankle System
Traditional 510(k) – 510(k) Summary**

510(K) SUMMARY

Sponsor	Exactech, Inc. 2320 NW 66th Court Gainesville, FL 32653 Phone: (352) 377-1140 Fax: (352) 378-2617 FDA Establishment Number 1038671
Contact Person	Pedro Ravelo Regulatory Affairs Specialist
Date	14 March 2023
Proprietary Name	Exactech® Vantage® Total Ankle System
Common Name	Ankle Arthroplasty Prosthesis
Regulation Number / Classification Name	21 CFR 888.3110 – Ankle joint metal/polymer semi-constrained cemented prosthesis
Device Class	Class II
Product Code	HSN – Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer
Classification Panel	Orthopedic

Device Description

The Vantage® Total Ankle System is a system of orthopedic implants intended for total ankle replacement. The system includes Tibial Plates, Tibial Inserts, Talar Components, and Locking Clips. This submission proposes three new components as line extensions of the Vantage Total Ankle System, which are modifications of their respective predicate components:

- 3D Tibial Plates
- 3D+ Tibial Plates
- 3D/3D+ Locking Clips

The proposed devices have the same indications for use and similar design characteristics as their predicate devices (cleared under K152217). The proposed tibial plates differ from the predicate in that they are additively manufactured, have minor geometrical modifications, and are offered in additional sizes. The proposed locking clips differ from the predicate in that they are offered in additional sizes.

Exactech® Vantage® Total Ankle System Traditional 510(k) – 510(k) Summary

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.

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K152217	Exactech® Vantage® Total Ankle System	Exactech, Inc

Legally Marketed Reference Devices

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K192097	Exactech® Equinox® Stemless Humeral Components	Exactech, Inc

Substantial Equivalence Discussion

The proposed Vantage 3D Tibial Plates, 3D⁺ Tibial Plates, and 3D/3D⁺ Locking Clips are made from Ti-6Al-4V ELI that conforms to ASTM F3001-14 or ASTM F136-13. The subject devices and their respective predicates have similar technological characteristics and the minor differences do not raise any different issues of safety and effectiveness. The rationale for substantial equivalence is based on consideration of the following device use, design characteristics, and performance requirements:

Indications for Use

The proposed and predicate devices have the same indications for use.

Materials

The proposed and predicate devices are composed of the same or similar biocompatible materials.

Design Features

The proposed and predicate devices have the same or similar design features.

Dimensions

The proposed and predicate devices are dimensionally comparable.

Sterilization

The proposed and predicate devices are provided sterile for single use only.

Performance Requirements

The proposed and predicate devices conform to the same recognized performance standards for total ankle replacement devices.

Exactech® Vantage® Total Ankle System Traditional 510(k) – 510(k) Summary

Non-Clinical Testing

The following non-clinical testing and engineering analyses were performed to demonstrate that the Exactech® Vantage® 3D Tibial Plates, 3D⁺ Tibial Plates and 3D/3D⁺ Locking Clips function as intended and are substantially equivalent to the identified predicate devices:

- Tibial Plate Fatigue Testing per ASTM F2665
- Tibial Plate Fixation Stability Testing
- Locking Mechanism Fatigue Testing
- Residual Particulate Count Studies
- Porous Surface Characterization Testing
 - Stereological Evaluation per ASTM F1854
 - Static Shear Testing per ASTM F1044
 - Tension Testing per ASTM F1147
 - Abrasion Resistance Testing per ASTM F1978
 - Shear Fatigue Testing per ASTM F1160
 - Compression Testing

The results of this non-clinical testing show that the strength of the Vantage 3D Tibial Plates, 3D⁺ Tibial Plates and 3D/3D⁺ Locking Clips is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices. Pyrogenicity testing was also conducted and demonstrates that the endotoxin limit is less than 20 EU/device.

Conclusion

Based on consideration of indications for use, technological characteristics, and results of non-clinical testing, it was concluded that the Exactech® Vantage® Total Ankle System is substantially equivalent to the identified predicate device.