October 3, 2024

Exactech Inc.
Liz Howell
Senior Regulatory Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K240393
Trade/Device Name: Exactech® TRULIANT® Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: February 8, 2024
Received: September 3, 2024

Dear Liz Howell:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240393

Device Name
Exactech® TRULIANT® Knee System

Indications for Use *(Describe)*
The Exactech® TRULIANT® Knee System is indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. It is also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

The TRULIANT Cemented Femoral Components, Tibial Inserts, and Tibial Trays are indicated for cemented use only. The TRULIANT Porous Femoral Components are indicated for cemented or cementless use. The TRULIANT Porous Tibial Trays are indicated for cemented or cementless use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Exactech® TRULIANT® Knee System
510(k) Summary

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

Phone: (352) 377-1140
Fax: (352) 378-2617

Applicant Contact: Liz Howell
Principal Regulatory Specialist
Telephone: (352) 377-1140
Fax: (352) 378-2617

Date: October 2, 2024

Device Trade Name: Exactech® TRULIANT® Knee System

Common Name: Total Knee Replacement system

Classification Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis

Regulation Number: 888.3565

Product Code: MBH, JWH

Legally Marketed Predicate Devices:

Predicate Number	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K182346	Truliant Porous Tibial Trays	MBH

Device Description Summary

The Exactech® Truliant® Knee System is a total knee replacement system comprised of femoral, tibial, and patellar implants. The proposed Porous Tibias are additional tibial tray implant variants intended for use with the Truliant Knee System. This submission proposes Truliant Porous Tibial Trays made from titanium alloy consolidated via direct metal laser sintering (DMLS). This submission additionally proposes a Porous Tibial Tray variant without screw holes, additional intermediate tray sizes, and minor geometric change(s) to the predicate Porous Tibial Tray design.

Exactech® TRULIANT® Knee System
510(k) Summary

Intended Use/Indications for Use
The Exactech® TRULIANT® Knee System is indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. It is also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

The TRULIANT Cemented Femoral Components, Tibial Inserts, and Tibial Trays are indicated for cemented use only. The TRULIANT Porous Femoral Components are indicated for cemented or cementless use. The TRULIANT Porous Tibial Trays are indicated for cemented or cementless use.

Indications for Use Comparison
The subject and the predicate devices have the same indications for use.

Technological Comparison
The proposed and predicate devices have the same intended use and basic fundamental scientific technology. The rationale for substantial equivalence of the proposed to the predicate cleared devices is based on consideration of the following aspects of the devices:

- The proposed and predicate devices are composed of similar biocompatible materials.
- The proposed and predicate devices have the same or similar design features.
- The proposed and predicate devices are provided sterile for single use only.
- The proposed and predicate devices conform to recognized performance standards for Knee replacement devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions
The following non-clinical testing and engineering analyses were performed to demonstrate that the Truliant Porous Tibial Trays perform as intended and are substantially equivalent to the identified predicate devices:

- Screw pull through testing
- Fatigue Testing per ASTM F1800-19e1
- Porous Structure Characterization per ASTM F1854-15, ASTM F1160-14(2017)e1, ISO 13179-1:2021(E), ASTM F1044-05(2017)e1, ASTM F1147-05(2017)e1, ASTM F1978-18, ISO 13314:2011
- Biocompatibility per ISO 10993-1:2018
- Bacterial endotoxins per USP <161>, USP <85> and ANSI/AAMI ST72

The differences in raw material, processing, porous structure, and device geometry do not change the intended use, safety, or performance requirements of the proposed devices, nor do they adversely affect their safety or effectiveness. This

Exactech® TRULIANT® Knee System
510(k) Summary

conclusion is based on consideration of the preclinical testing and analysis including fatigue, mechanical, material characterization, porous structure characterization, biocompatibility assessment and testing completed to establish substantial equivalence of the proposed devices to the predicate devices.