July 17, 2023

Elizabeth Howell
Senior Regulatory Specialist
2320 NW 66th Ct
Gainesville, Florida 32653

Re: K223252
Trade/Device Name: TRULIANT® E-PX Tibial Inserts; TRULIANT® E-PX Patellas
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: June 13, 2023
Received: June 13, 2023

Dear Elizabeth 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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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)*
K223252

Device Name
TRULIANT® E-PX Tibial Inserts;
TRULIANT® E-PX Patellas

Indications for Use *(Describe)*
The TRULIANT E-PX Tibial Inserts and Patellas are 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. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

The TRULIANT E-PX Patellas are intended 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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TRULIANT® E-PX Tibial Inserts and Patellas
510(k) Summary

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

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

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

Date: July 14, 2023

Device Trade Name: TRULIANT® E-PX Tibial Inserts; TRULIANT® E-PX Patellas

Common Name: Total Knee Prosthesis

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Regulation Number: 888.3560

Product Code: JWH

Legally Marketed Predicate Devices:

Predicate Number	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K152170	Exactech Optetrak Logic Enhanced Assembly	JWH
K171045	Exactech Truliant Line Extensions	JWH
K932690	Exactech Cruciate Retaining Cemented Total Knee System	JWH
K160484	Optetrak Advanced Patella	JWH
K150890	Exactech Optetrak Logic CC	JWH
K211877	Klassic Knee System	JWH

Device Description Summary

The TRULIANT Knee System is a system of orthopedic implants intended for total knee replacement. The system includes Femoral components, Tibial Trays, Tibial Inserts, and Patellas. The Tibial Inserts and Patellas used in the TRULIANT Knee system currently are constructed of compression molded UHMWPE and extruded UHMWPE respectively. This submission proposes TRULIANT Tibial Inserts and Patellas made from UHMWPE containing vitamin E. This submission additionally proposes minor geometric change(s) to all Tibial Insert devices as well as additional intermediate TRULIANT CC Tibial Insert size options.

TRULIANT® E-PX Tibial Inserts and Patellas
510(k) Summary

Intended Use/Indications for Use

The TRULIANT E-PX Tibial Inserts and Patellas are 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. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

The TRULIANT E-PX Patellas are intended for cemented use only.

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 similar 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 subject and the predicate devices are composed of the similar biocompatible materials.
- The subject and the predicate devices have 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 Exactech TRULIANT Tibial Inserts and Patellas perform as intended and are substantially equivalent to the identified predicate devices:

- Material Characterization
- Wear
- Fatigue
- Range of Motion
- Tibial-femoral stability characteristics
- Tibial modular disassembly characteristics
- Biocompatibility
- Bacterial endotoxins

The differences in raw material and 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 conclusion is based on consideration of the preclinical testing and analysis including material characterization, biocompatibility assessment and testing and mechanical testing and analysis completed to establish substantial equivalence of the proposed devices to the predicate devices.