September 28, 2018

Exactech, Inc.
Patrick Hughes
Regulatory Affairs Manager
2320 NW 66th CT
Gainesville, Florida 32653

Re: K181794
Trade/Device Name: Truliant Porous Femoral Components
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: September 5, 2018
Received: September 7, 2018

Dear Patrick Hughes:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S
2018.09.28 14:18:50 -04'00'

FOR 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181794

Device Name
Truliant Porous Femoral Components

Indications for Use *(Describe)*

The TRULIANT Femoral Components, Tibial Inserts, and Tibial Trays 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 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.

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® Porous Femoral Components
Special 510(k) – 510(k) Summary

Sponsor: Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

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

FDA Establishment Number 1038671

Contact: Patrick Hughes
Regulatory Affairs Manager

Date: July 2, 2018

Trade or Proprietary or Model Name(s):
Exactech® Truliant® Porous Femoral Components

Common Name:
Uncemented or Cemented Total Knee Prosthesis

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

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Product Code:
MBH, JWH

Classification Panel:
Orthopedic

Regulation Number

888.3565
888.3560

Device Class
II

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K140302	Optetrak Logic Porous Femoral Components	Exactech, Inc

Exactech® Truliant® Porous Femoral Components
Special 510(k) – 510(k) Summary

Indications for Use:
The TRULIANT Femoral Components, Tibial Inserts, and Tibial Trays 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 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.

Device Description:
Truliant femoral components are for use in resurfacing femoral bone as part of tri-compartmental total knee arthroplasty employing modular components from the Optetrak / Optetrak Logic and Truliant device families.

Proposed Truliant porous femoral components represent modifications to Optetrak Logic porous femoral components cleared per 510(k) K140302. The proposed Truliant porous femoral components are identical to other Truliant femoral components but employ a porous structure identical to that used for the cited predicate femoral components and can be implanted as part of an uncemented surgical approach.

Proposed and predicate devices operate using the same fundamental scientific technology, have the same intended use and design features, employ the same materials of construction, are offered in similar product size scopes, are implanted using similar surgical techniques and the same or similar instrumentation, have equivalent Indications for Use statements, and, size for size, are compatible with the same Optetrak, Optetrak Logic, and Truliant patellar and tibial components.

Exactech® Truliant® Porous Femoral Components
Special 510(k) – 510(k) Summary

Testing Description:

This submission references results for:

- Simulated use activities
- Surgeon expert evaluation
- Engineering analysis of device press-fit.

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Truliant components meet recommended limits per FDA's *Guidance Document Submission and Review of Sterility Information in Premarket (510(k)) Submission for Devices Labeled as Sterile*.

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate proposed Truliant porous femoral components are substantially equivalent to cited cleared predicate Optetrak Logic porous femoral components.