DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 23, 2017

Exactech Inc
Patrick Hughes
Senior Regulatory Affairs Specialist
2320 N.W. 66th Ct
Gainesville, Florida 32653

Re: K170240
Trade/Device Name: Truliant Femoral Components
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: January 24, 2017
Received: January 26, 2017

Dear Mr. 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. 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); 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" (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 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,

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)*
K170240

Device Name
Truliant 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 Femoral Components, Tibial Inserts, and Tibial Trays are 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® Truliant™ Femoral Components
Special 510(k) – 510(k) Summary of Safety and Effectiveness

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
Senior Regulatory Affairs Specialist

Date: January 24, 2017

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

Common Name:
Cemented Total Knee Prosthesis

Classification Name:
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer

Product Code:
JWH

Classification Panel:
Orthopedic

Regulation Number
888.3560

Device Class
II

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K153776	Exactech One Logic Femoral Components	Exactech, Inc

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-

Exactech® Truliant™ Femoral Components
Special 510(k) – 510(k) Summary of Safety and Effectiveness

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 Femoral Components, Tibial Inserts, and Tibial Trays are indicated for cemented use only.

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.

Truliant femoral components represent modifications to Exactech One Logic femoral components cleared per 510(k) K153776. The proposed Truliant femoral components are identical to predicated One Logic femoral components, with the following key exceptions:

- Tapered anterior chamfer and patella flange to reduce the appearance of implant / bone overhang
- Patella flange cement pocket has been modified to increase cement / bone contact area

Additional modifications have been made to facilitate manufacturing.

Like other femoral implants in compatible device families, One Logic femoral components are made from CoCr alloy and are designed to articulate on an ultra-high molecular weight polyethylene tibial insert seated in a metal tibial tray.

Truliant femoral components have the same basic features and articulating surface finish as predicate One Logic femoral components while providing surgeons with an option for a femoral implant with a patella flange that has been comparatively streamlined in the medial-lateral aspects. The articulating congruence featured in all Optetrak and Optetrak Logic femoral-tibial condyle contact is maintained for Truliant femoral components. Cruciate-retaining Truliant femoral components also feature the same patella entry / exit point at the distal trochlear groove featured on predicate One Logic femoral components and intended to enhance patella transition.

The proposed devices operate using same fundamental scientific technology, have the same intended use and design features, employ the same materials of construction, are offered in the same product size scopes, and are implanted using a similar surgical technique and the same or similar instrumentation. The only modifications proposed by this submission are dimensional.

Exactech® Truliant™ Femoral Components
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Testing Description:
This submission includes results for mechanical patellofemoral constraint and contact pressure testing. Results conclude the proposed Truliant devices do not represent a new worst-case for risks associated with patellofemoral contact.

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 devices are substantially equivalent to cited cleared predicate One Logic devices.