November 26, 2018

Exactech, Inc.
% Meredith May
Vice President
Empirical Consulting LLC
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K182346
Trade/Device Name: TRULIANT Porous Tibial Tray and Exactech Alteon Bone Screws
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Codes: MBH, JWH
Dated: August 24, 2018
Received: August 28, 2018

Dear Meredith May:

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,

Daniel S. Ramsey -S
2018.11.26 11:34:06 -05'00'

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 on last page.

510(k) Number *(if known)*
K182346

Device Name
TRULIANT Porous Tibial Tray

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.

All TRULIANT Femoral Components, Tibial Inserts, and Tibial Trays are indicated for cemented use only, except the TRULIANT Porous Tibial Trays, which 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.

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 on last page.

510(k) Number *(if known)*
K182346

Device Name
Exactech® Alteon® Bone Screws

Indications for Use *(Describe)*

Exactech Alteon Bone Screws are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Exactech Alteon Bone Screws are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

The Exactech Alteon Bone Screws are also 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.

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.

510(K) SUMMARY

Submitter's Name:	Exactech, Inc.
Submitter's Address:	2320 N.W. 66th Court Gainesville, Florida 32653
Submitter's Telephone:	(352) 378-2617
Contact Person:	Meredith Lee May MS, RAC Empirical Consulting 719.337.7579 MMay@EmpiricalConsulting.com
Date Summary was Prepared:	24-Aug-18
Trade or Proprietary Name:	TRULIANT Porous Tibial Tray Alteon Bone Screws
Common or Usual Name:	Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/ Metal/Polymer Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Classification:	Class II per 21 CFR §888.3565 and 21 CFR §888.3560
Product Code:	MBH, JWH
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The tibial tray implant and its porous structure is manufactured from Ti-6Al-4V titanium alloy using electron beam melting (EBM) technology. This product line represents a scope extension of the Truliant knee implant system. The previously cleared Alteon Bone Screws are now cleared for use with the TRULIANT Porous Tibial Trays.

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.

All TRULIANT Femoral Components, Tibial Inserts, and Tibial Trays are indicated for cemented use only, except the TRULIANT Porous Tibial Trays, which are indicated for cemented or cementless use.

Exactech Alteon Bone Screws are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Exactech Alteon Bone Screws are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

The Exactech Alteon Bone Screws are also 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.

TECHNOLOGICAL CHARACTERISTICS

TRULIANT Porous Tibial Tray and Alteon Bone Screws are made from Ti-6Al-4V that conforms to ASTM F2924-14 or ASTM F136-13. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Method of manufacture
- Mechanical strength

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K123486	Triathlon Tritanium Tibial Baseplates	Howmedica Osteonics Corp (marketed by Stryker)	Primary
K120990	NexGen® LCCK Trabecular Metal Coupled Tibial Cones	Zimmer Trabecular Metal Technology, Inc.	Additional
K153595	Optetrak Logic Metaphyseal Cones	Exactech, Inc.	Additional
K141797	Alteon 6.5mm Bone Screws	Exactech, Inc.	Additional

PERFORMANCE DATA

The TRULIANT Porous Tibial Tray has been tested in the following test modes:

- Tibial tray fatigue per ASTM F1800-12
- Shear fatigue of an EBM porous structure per ASTM F1160-14 (2017)
- Static shear of an EBM porous structure per ASTM F1044-05 (2017)
- Static tension of an EBM porous structure per ASTM F1147-95 (2017)
- Static compression of an EBM porous structure per ASTM E9-09 (2018)
- Porous coating characterization per ASTM F1854-15

The results of this non-clinical testing show that the strength of the TRULIANT Porous Tibial Tray 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

The overall technology characteristics and mechanical performance data lead to the conclusion that the TRULIANT Porous Tibial Tray and Alteon Bone Screws are substantially equivalent to the predicate device.