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

March 18, 2016

Exactech Incorporated
Mr. Patrick Hughes
Senior Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K160484
Trade/Device Name: Optetrak Advanced Patella
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: February 17, 2016
Received: February 22, 2016

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 Parts 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" (21CFR 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 yours,

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)*
K160484

Device Name
Optetrak Advanced Patella

Indications for Use *(Describe)*
The OPTETRAK Comprehensive Knee Systems 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. In the USA, the OPTETRAK Comprehensive Knee Systems are indicated for cemented use only, except for the OPTETRAK Logic PS and CR Porous Femoral Components, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Exactech® Optetrak® Advanced Patella
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: February 18, 2016

Trade or Proprietary or Model Name(s):
Exactech® Optetrak® Advanced Patella

Common Name:
Cemented Total Knee Prosthesis

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

Classification Panel:
Orthopedic

Product Code:
JWH

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
K954208	Optetrak Constrained Condylar Knee	Exactech, Inc

Exactech® Optetrak® Advanced Patella
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Indications for Use:
The OPTETRAK Comprehensive Knee Systems 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. In the USA, the OPTETRAK Comprehensive Knee Systems are indicated for cemented use only, except for the OPTETRAK Logic PS and CR Porous Femoral Components, which are indicated for cemented or cementless use.

Device Description:
Optetrak Advanced Patella implants represent dimensional modifications to "classic" Optetrak patella components. Like the predicate devices, Optetrak Advanced Patella implants are intended for resurfacing the patella during tri-compartmental total knee arthroplasty with other Optetrak and Optetrak Logic components. Optetrak Advanced Patella implants are designed to provide expanded options to help surgeons optimize bone coverage while keeping the same basic features and device compatibility as predicate "classic" Optetrak patella implants.

Technological Characteristics
The Optetrak Advanced Patella is an orthopedic implant made from ultra-high molecular weight polyethylene. It features the same spherical articulating geometry, mating device congruence, and bone-apposing fixation features as other Optetrak patella implants, and is provided in a similar product scope. Where other Optetrak patella components are circular, the Optetrak Advanced Patella features an increase in medial-lateral area relative to the proximal-distal aspect on the bone-apposing face of the implant and an asymmetric, "avocado"-shaped perimeter. Like other Optetrak patella implants, the Optetrak Advanced Patella is intended for cemented fixation.

Testing Description:
This submission reports results for the following mechanical testing:

- Patellofemoral contact pressure analysis

Reported results show the Optetrak Advanced Patella Devices do not represent a new worst-case

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate proposed Optetrak Advanced Patella devices are substantially equivalent to cited cleared predicate Optetrak patella components.