DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 25, 2016

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

Re: K153595
Trade/Device Name: Optetrak Logic Metaphyseal Cones
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 24, 2016
Received: February 26, 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)*

K153595

Device Name
Optetrak Logic Metaphyseal Cones

Indications for Use *(Describe)*

The Optetrak Logic Femoral and Tibial Metaphyseal Cones 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 Cones are intended for press-fit or cemented fixation with the proximal tibial or distal femur. The final implant construct is completed by cementing a tibial tray or femoral component in place.

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 Logic® Metaphyseal Cones
## Traditional 510(k) – 510(k) Summary of Safety and Effectiveness

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

Phone: (352) 327-4762
Fax: (352) 378-2617

FDA Establishment Number 1038671

**Contact:** Patrick Hughes
Senior Regulatory Affairs Specialist

**Date:** March 25, 2016

**Trade of Proprietary or Model Name(s):**
Exactech® Optetrak Logic® Metaphyseal Cones

**Common Name:**
Knee System Augments

**Classification Name:**
Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer (CFR 888. 888.3560; Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, Class II, Product Code JWH)

**Information on devices to which substantial equivalence is claimed:**

| *510(k) Number* | *Trade or Proprietary Model Name* | *Manufacturer* |
|---|---|---|
| K143393 | Triathlon® Tritanium® Cone Augments | Stryker |

**Reference devices:**

| *510(k) Number* | *Trade or Proprietary Model Name* | *Manufacturer* |
|---|---|---|
| K102975 | Novation® Crown Cup® With InteGrip™ Acetabular Shell, Cluster-Hole | Exactech, Inc. |

# Exactech® Optetrak Logic® Metaphyseal Cones
# Traditional 510(k) – 510(k) Summary of Safety and Effectiveness

**Indications for Use:**
The Optetrak Logic Metaphyseal Cones 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 augments are intended for press-fit fixation with the proximal tibial or distal femur. The final implant construct is completed by cementing a tibial tray or femoral component in place.

**Device Description:**
Optetrak Logic Metaphyseal Cones are designed to fill tibial and femoral bone voids during revision or complex primary surgery in the case of severe bone loss. Specifically, Optetrak Logic Metaphyseal Cones are designed to enhance fixation in primary or revision total knee arthroplasty (TKA) patients who have Anderson Orthopaedic Research Institute (AORI) type II and III tibial and femoral defects by providing stability to total knee implants via the metaphysis.

**Testing:**
This submission includes or references the following non-clinical testing:

- Fatigue testing
- Mating analysis
- Cadaveric implantation and surgeon assessment
- Biocompatibility assessment
- Compressive plastic deformation testing
- Abrasion resistance
- Static tensile strength testing
- Shear resistance
- Porous structure characterization

**Substantial Equivalence Conclusion:**
A comparison of key features and attributes included in this submission demonstrates the proposed Optetrak Logic Metaphyseal Cones devices are substantially equivalent to predicate Triathlon Tritanium Cone Augments, legally marketed per 510(k) submission K143393.