**Exactech® Optetrak Logic® 17mm & 19mm Thick Inserts**
**Traditional 510(k) – 510(k) Summary**

**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:** July 10, 2013

OCT 11 2013

**Trade of Proprietary or Model Name(s):**
Exactech Optetrak Logic 17mm & 19mm Thick Inserts

**Common Name:**
Total Knee Arthroplasty – Tibial Inserts

**Classification Name:**
Cemented total knee prosthesis (CFR 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 or Model Name | Manufacturer |
|---|---|---|
| K093360 | Optetrak Logic PS | Exactech, Inc. |
| K110547 | Optetrak Logic PSC | Exactech, Inc. |
| K111400 | Optetrak Logic CR | Exactech, Inc. |
| K121307 | Optetrak Logic CR Sizes 0 & 6 | Exactech, Inc. |
| K123342 | Optetrak Logic CRC | Exactech, Inc |
| K933610 | Exactech Cemented Total Knee System Tibial Components | Exactech, Inc |
| K932776 | Optetrak Cruciate Retaining Tibial Components | Exactech, Inc |

**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 System is indicated for cemented use only.

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**Device Description:**
The proposed Optetrak Logic 17mm & 19mm Thick Inserts are modifications to Optetrak Logic ultra high molecular weight polyethylene (UHMWPE) tibial insert components cleared per 510(k)s K093360, K110547, K111400, K121307, and K123342.

This submission proposes adding 17mm and 19mm tibial insert options to the existing 9mm-15mm range of Optetrak Logic insert thicknesses. The 17mm and 19mm thick inserts will be provided across the current component size range (size 0 through size 6). Like the predicate devices, the proposed inserts are used in total knee arthroplasty (TKA) with metal femoral components and tibial trays. The thicker inserts are proposed for both posterior-stabilized (Logic PS, Logic PSC) and cruciate-retaining (Logic CR, Logic CRC) product options.

**Comparison of Technological Characteristics**
The predicate and proposed devices have the same intended use and basic fundamental scientific technology. The intended use of the modified device, as described in the labeling, has not changed as a result of the proposed modifications. The modified devices share the following similarities with the predicate devices:

- Indications for use
- Design features (including mating geometry, locking mechanism, and articulating geometry)
- Material (UHMWPE per ASTM F648)
- 8-year shelf life
- Packaging and sterilization materials and processes (gamma radiation sterilization to a sterility assurance level of $10^{-6}$)
- Use at the same site in the body for the same purpose (TKA)

The proposed components are not being submitted as the result of a recall or any corrective action related to the Optetrak product lines.

**Non-Clinical Performance Data**
Table 1 shows non-clinical performance data provided, cited, or referenced in this submission to support a conclusion of substantial equivalence:

**Table 1: Optetrak Logic 17mm & 19mm Thick Tibial Inserts Testing**

| Evaluation | Activity |
|---|---|
| Locking stability | Anterior/posterior liftoff/dissociation testing |

**Substantial Equivalence Conclusion:**
Comparison analysis and results of engineering studies referenced in this 510(k) submission demonstrate proposed Optetrak Logic 17mm & 19mm Thick Tibial Inserts are substantially equivalent to predicate Optetrak Logic tibial inserts cleared per 510(k)s K093360, K110547, K111400, K121307, K123342, K933610, and K932776.

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

October 11, 2013

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

Re: K132161
Trade/Device Name: Exactech® Optetrak Logic® 17mm & 19mm Thick Inserts
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: September 19, 2013
Received: September 20, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Exactech® Optetrak Logic® 17mm & 19mm Thick Inserts**
**Special 510(k) – Indications for Use**

**510(k) Number:** K132161

**Device Name:** Exactech® Optetrak Logic® 17mm & 19mm Thick Inserts

**INDICATIONS**

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 System is indicated for cemented use only.

**Prescription Use** X **and/or** **Over-The-Counter Use**
**(Part 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices