K121307 (1/2)

**Exactech® Optetrak® Logic® CR Knee System, Sizes 0 and 6**
**Special 510(k) – 510(k) Summary of Safety and Effectiveness**

MAY 31 2012

**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
Regulatory Affairs Specialist

**Date:** April 27, 2012

**Trade or Proprietary or Model Name(s):**
Exactech® Optetrak® Logic® CR Knee System

**Common Name:**
Cemented Total Knee Prosthesis

**Classification Name:**
21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

**Product Code:**
JWH – prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer

**FDA Classification:**
Class II

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

| 510(k) Number | Trade or Proprietary or Model Name | Manufacturer |
|---|---|---|
| K111400 | Optetrak Logic CR Knee System | Exactech |

K121307(2/2)

**Exactech® Optetrak® Logic® CR Knee System, Sizes 0 and 6**
**Special 510(k) – 510(k) Summary of Safety and Effectiveness**

**Indications for Use:**
The Optetrak Logic Total Knee System is 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 Logic Total Knee System is indicated for cemented use only.

**Device Description:**
Proposed size 0 and size 6 Optetrak Logic CR Knee System components are line extensions to the Optetrak Logic CR Knee System cleared per 510(k) #K111400.

The predicate and proposed devices have the same intended use and basic fundamental scientific technology and share the following similarities:

- the same indications for use
- the same design features
- the same materials
- the same shelf life
- packaging and sterilization using the same materials and processes
- compatible with the same corresponding Optetrak Logic tibial trays

The size 0 and 6 Optetrak Logic CR Knee System components are not being submitted as the result of a recall or any corrective action related to the Optetrak product lines.

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

**Table 1: Optetrak Logic CR Performance Data**

| Evaluation | Activities Performed |
|---|---|
| Logic CR size 0 and size 6 (11mm) insert performance equivalency | Mechanical testing to assess and compare peak contact pressures. |
| Logic CR size 6 (9mm) insert performance equivalency | Mechanical testing to assess and compare peak contact pressures. |

**Substantial Equivalence Conclusion:**
Results of engineering studies referenced in this 510(k) submission demonstrate proposed size 0 and size 6 Optetrak Logic CR Knee System devices are substantially equivalent to cited cleared predicate devices.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

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

MAY 3 1 2012

Re: K121307
Trade/Device Name: Exactech® Optetrak® Logic® CR Knee System
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: April 27, 2012
Received: May 1, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

**Exactech® Optetrak® Logic® CR Knee System, Sizes 0 and 6**
**Special 510(k) – Indications for Use**

**510(k) Number:** K121307

**Device Name: Exactech® Optetrak® Logic® CR Knee System**

**INDICATIONS**

The OPTETRAK Logic Total Knee System is 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 Logic Total 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)**

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121307