K093360 #1/2

Exactech® Optetrak® Logic™ Total Knee System
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
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FDA Establishment Number 1038671

Contact: Patrick Hughes
Regulatory Affairs Specialist

JAN 1 1 2010

Date: January 6, 2010

Trade or Proprietary or Model Name(s):
Exactech® Optetrak® Logic™ Total Knee System

Common Name:
Cemented Total Knee Prosthesis

Classification Name:

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Information on devices to which Substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K933610	Optetrak Total Knee Trapezoidal Cemented Tibial Components	Exactech, Inc.
K932776	Optetrak Total Knee System Cruciate Retained Titanium Back Tibial Components	Exactech, Inc.
K033883	Optetrak Total Knee System Hi-Flex Knee Components	Exactech, Inc.
K933494	Optetrak Posterior Stabilized Cemented Total Knee	Exactech, Inc.
K032606	Optetrak Asymmetric Femoral Component	Exactech, Inc.

K093360 #2/2

Exactech® Optetrak® Logic™ Total Knee System
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.

The Optetrak Logic Total Knee System is indicated for cemented use only.

Device Description:
The proposed Optetrak Logic Total Knee System half-size finned and trapezoidal tibial trays are modifications to the existing Optetrak Total Knee System Cruciate Retained Titanium Back Tibial Components (K932776) and Optetrak Total Knee Trapezoidal Cemented Tibial Components (933610), respectively. The proposed Optetrak Logic Total Knee System tibial inserts and femoral components are modifications to the existing Optetrak Total Knee System Hi-Flex Knee Components (K033883).

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
- similar design features
- incorporate the same materials
- the same shelf life
- are packaged and sterilized using the same materials and processes.

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Optetrak Logic Total 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 W-O66-0609
Silver Spring, MD 20993-0002

Exactech Inc.
% Mr. Patrick Hughes
2320 N.W. 66th Court
Gainesville, Florida 32653

JAN 1 1 2010

Re: K093360
Trade/Device Name: Exactech® Optetrak® Logic™ Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: December 09, 2009
Received: December 14, 4009

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.

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,

Barbara Bucher for

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™ Total Knee System
Special 510(k) – Indications for Use

510(k) Number: K093360

Device Name: Exactech® Optetrak® Logic™ Total 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.

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)

for mxm

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

510(k) Number K093360