K033883

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FEB 13 2004

Exactech Optetrak® Total Knee System
Line Extension-Optetrak® HI-FLEX Knee Components
Special 510(k)

Summary of Safety and Effectiveness

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653
Phone: (352) 377-1140
Fax: (352) 378-2617

FDA Establishment Number: 1038671

Contact: Dr. Gary Miller
Vice President of Research and Development

Date: _____

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Classifications / Proprietary Names:

Classification Name:	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, cemented, Polymer/Metal/Polymer
Trade / Proprietary Model Name:	Optetrak® Total Knee System • *HI-FLEX Asymmetric Posterior-Stabilized Cemented Femoral Components* • *HI-FLEX Posterior-Stabilized Tibial Insert Components*
Product Code:	JWH
C.F.R. Section:	888.3560
Device Class:	II
Classification Panel:	Orthopedic

Exactech Legally Marketed Devices for Substantial Equivalence Comparison:

Model	510(k) Number
Optetrak® Total Knee System Tibial Component	K933610
Optetrak® Size 0 and 1 Delta Line Extension	K011976
Optetrak® Total Knee Asymmetric Femoral Components	K032606
Optetrak® B-Series Total Knee System	K010434

Device Information:

INTENDED USE

The Optetrak® HI-FLEX Asymmetric Posterior-Stabilized Cemented Femoral Components (herein referred to as the Optetrak® HI-FLEX PS Femoral Components) and Optetrak® HI-FLEX Posterior-Stabilized Tibial Inserts (Herein referred to as the HI-FLEX PS Tibial Inserts) are intended to be used with an Optetrak® Tibial Tray to replace the patient's distal femur and proximal tibia during primary or revision total knee arthroplasty. The Optetrak® HI-FLEX PS Femoral components are intended for use when needed to closely

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match the geometry of the patient's resected distal femur and allows for more flexion than the standard Optetrak® components.

The Optetrak® HI-FLEX PS Tibial Insert is intended for use with the Optetrak® HI-FLEX PS Femoral components to afford the patient a higher degree of flexion than the standard Optetrak® femoral/tibial insert combination.

The proposed components are intended for use in total knee arthroplasty procedures in which the Posterior Cruciate Ligament (PCL) must be sacrificed.

All proposed femoral components are intended for cemented use only.

INDICATIONS

The OPTETRAK® Total 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.

CONTRAINDICATIONS

The OPTETRAK® Total Knee Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, patients without sufficient soft tissue integrity to provide adequate stability, and in patients with either mental or neuromuscular disorders that do not allow control of the knee joint, and in patients whose weight, age, or activity level might cause extreme loads and early failure of the system.

Optetrak® HI-FLEX Tibial Inserts must be used with Optetrak® HI-FLEX Femoral Components.

CAUTION: In the USA, for cemented use only.

Device Modifications

The device modifications to the femoral components presented in this Special 510(k) represent changes to the Optetrak® Asymmetric (AK), Posterior-Stabilized, Cemented

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Femoral Components (K032606) and the Optetrak® B-Series Posterior-Stabilized Femoral Component (K010434). These changes represent a combination of:

1. The condyle, anterior cam, asymmetric flange and PCL stabilizing box geometries of the Optetrak® AK Femoral components, and
2. The Posterior condyle radius and cam geometries of the Optetrak® B-Series Femoral Component

The device modifications to the tibial insert components presented in this Special 510(k) represent changes to the Optetrak® Posterior-Stabilized Tibial Inserts (K011976 and K933610) and changes to the Optetrak® B-series Tibial Inserts (K010434). These changes represent a combination of:

1. The articulating surfaces, mating geometry and anterior spine geometry of the Optetrak® Posterior-Stabilized Tibial Inserts, and
2. The posterior portion of the spine and the posterior scallops of the Optetrak® B-Series Tibial Insert Component

No changes were made to the patellar or tibial tray components of the Optetrak® Total Knee System.

PERFORMANCE DATA SUMMARY

Verification and Validation analyses were conducted to verify that the implant performance would be adequate for anticipated *in vivo* loading.

We conclude that the Optetrak® HI-FLEX PS Femoral Components and the Optetrak® HI-FLEX PS Tibial Inserts are substantially equivalent to other devices legally marketed in the United States, most notably Exactech's predicate Optetrak® AK Femoral and Optetrak® Posterior-Stabilized tibial insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2004

Gary J. Miller, Ph.D.
Vice President of Research and Development
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K033883
Trade/Device Name: Optetrak® 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: January 15, 2004
Received: January 16, 2004

Dear Dr. Miller:

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.

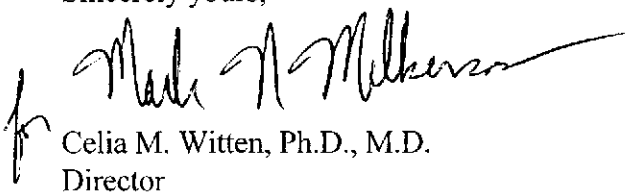
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech

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Exactech Optetrak® Total Knee System
Line Extension-Optetrak® HI-FLEX Knee Components
Special 510(k)

Indications for Use

510(k) Number: #K033883

Device Name: Optetrak® Total Knee System

- *HI-FLEX Asymmetric Posterior-Stabilized Cemented Femoral Components*
- *HI-FLEX Posterior-Stabilized Tibial Insert Components*

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CAUTION: In the USA, for cemented use only.

Prescription Use (Part 21 CFR 801 D) ___X___ or Over the Counter Use _____

(Division Sign-Off) Please do not write below this line - use another page if needed.

Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K033883

EXACTECH exists to improve the quality of life for individuals by maintaining their activity and independence. We do this through innovative ideas, high-quality products, education and commitment to service.