K032606

SEP 2 3 2003

# Exactech® Optetrak® Total Knee System
# Line Extension – Optetrak® Femoral Components
# Special 510(k)

## Summary of Safety and Effectiveness

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**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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## Summary of Safety and Effectiveness

**Classifications / Proprietary Names:**

| | |
|---|---|
| Classification Name: | Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, cemented, Polymer/Metal/Polymer |
| Trade / Proprietary Model Name: | Optetrak® Total Knee System<br>• *Asymmetric Femoral Components*<br>• *Size 6 Posterior-Stabilizing, Cemented Femoral Component* |
| 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® Cruciate Retaining Cemented Femoral Component | K932690 |
| Optetrak® Posterior Stabilizing Cemented Femoral Component | K933494 |
| Optetrak® Cruciate Retaining Porous-Coated Femoral Component | K935726 |
| Optetrak® Size 0 and 1 Delta Line Extension | K011976 |

**Device Information:**

**INTENDED USE**

The Optetrak® Femoral components are intended to replace the patient's distal femur during primary or revision total knee arthroplasty. The Optetrak® Asymmetric Femoral components are intended for use when needed to more closely match the geometry of the patient's resected distal femur. This change results in separate components for the right and left knees. The Asymmetric, Cruciate-Retaining Cemented components and the Asymmetric, Cruciate-Retaining, Porous-Coated Femoral Components are intended for

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use in total knee arthroplasty procedures in which the Posterior Cruciate Ligament (PCL) is preserved.

The Optetrak® Size 6 Posterior-Stabilizing, Cemented Femoral Component and Asymmetric, Posterior-Stabilizing Femoral components are intended to replace the function of the PCL during a total knee arthroplasty in which the 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.

*CAUTION: In the USA, for cemented use only.*

**Device Modifications**

The device modifications presented in this Special 510(k) represent changes to the posterior stabilized, cruciate-retaining cemented, and cruciate-retaining porous coated femoral components of the Optetrak® Total Knee System (K932690, K933494, K935726, K011976). These changes include:

1. Modification of the patellar flange to create an asymmetric femoral component
2. Addition of a larger size posterior-stabilized, cemented (symmetric) femoral component

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

**Device Modifications – Optetrak® Asymmetric Femoral Components (Optetrak® AK):**

The differences in design features between the proposed Optetrak® AK Femoral and predicate Optetrak® Femoral include the following:

1. Changes to the anterior flange to make the component asymmetric by:
    a. Tilting the flange laterally, and
    b. Angling the proximal edge of the flange medially.
2. Adjustments to the patella groove edges by:
    a. Increasing the edge radii resulting from the intersections of the patella groove and the trochlear condyles to smooth the edges, and
    b. Slightly lowering the profile height of the medial trochlear condyle in the proximal area as a result of the tilting of the flange.

**Device Modifications - Optetrak® Size 6 Posterior-Stabilized, Cemented Femoral Component:**

The difference in design between the proposed size 6 femoral component and the predicate femoral components consists of a size increase in the overall geometry of the component, resulting in:

1. An increase in the overall anterior-posterior dimension of four (4) millimeters
2. An increase in the overall medial-lateral dimension of five (5) millimeters

**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® Asymmetric Femoral Components and the Size 6 Posterior-Stabilizing Cemented Femoral Component are substantially equivalent to other devices legally marketed in the United States, most notably Exactech's predicate Optetrak® femoral components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2003

Mr. Martin Sprunck
Regulatory Representative
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

Re: K032606
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: August 20, 2003
Received: August 25, 2003

Dear Mr. Sprunck:

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,

for Mark N Melkerson

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

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## Indications for Use

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**510(k) Number:** K032606

**Device Name:**

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*CAUTION: In the USA, for cemented use only.*

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032606

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over the Counter Use _____