K030686 page 1 of 3

Exactech® Optetrak® Total Knee System
Line Extension – Molded Metal-back Tibial Component
Special 510(k)

APR 0 2 2003

Summary of Safety and Effectiveness

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Classification Name: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer

Trade/Proprietary Model Names: Optetrak Total Knee System
Molded Metal-back Tibial Component

Product Code: JWH

C.F.R. Section: 888.3560

Device Class: II

Classification Panel: Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer	510(k)#
Optetrak® Total Knee – Posterior Stabilized Tibial Tray Insert Components	Exactech	K933610
Exactech Cruciate Retaining Cemented Tibial Components – Cemented Finned Tibial Tray Components	Exactech	K932776
Optetrak® Total Knee System: Size 0/1 Delta Line Extension – Cemented Finned Tibial Tray Components and Posterior Stabilized Tibial Inserts	Exactech	K011976
AGC Total Knee Prosthesis - Posterior-Stabilized Tibial Components	Biomet	K833921
Insall/Burstein Constrained Total Condylar Knee	Zimmer	K810520

In materials and design, the proposed Molded Metal-back Tibial components are a combination of:

1) The articulating surfaces of the Exactech Optetrak Tibial Tray Insert components (K933610 and K011976)
2) The tibial stem of the Cemented Finned Tibial Tray components (K932776 and K011976)

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Intended Use

The Molded Metal-back Tibial components are intended to replace the patient's proximal tibia during primary or revision total knee arthroplasty. This device has been designed to substitute for the posterior stability of the Posterior Cruciate Ligament (PCL) and is intended for cemented application.

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, modular tibial insert and finned tibial tray components of the Optetrak Total Knee (K932776, K933610 and K011976). No changes were made to the femoral or patellar components of this system.

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The proposed device modifications involve:

1) Modification to the portion of the modular assembly distal to the proximal articulating surface and proximal to the distal finned stem.
2) Revised cement fixation undercuts on the distal portion of the component
3) Integration of geometric undercuts to form a mechanical interlock between the UHMWPE and metallic portions of the component
4) A change in material of the finned stem portion from titanium alloy to cobalt-chromium (CoCr)

No modifications have been made to the articular surface of the UHMWPE that interfaces with the femoral components. Nor have any configuration changes been made to the finned stem portion of the tibial bone interface.

There have been no changes to the material of the predicate Optetrak Total Knee bearing surface. Like the predicate Optetrak Total Knee tibial inserts, the proposed bearing surface is manufactured of Ultra-High Molecular Weight Polyethylene (UHMWPE) conforming to ASTM F648.

PERFORMANCE DATA SUMMARY

Functional testing was conducted to verify that the implant performance would be adequate for anticipated *in vivo* loading.

We conclude that the Molded Metal-back Tibial Components are substantially equivalent to other devices legally marketed in the United States, most notably Exactech's predicate Optetrak products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 02 2003

Mr. Martin Sprunck
Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K030686
Trade/Device Name: Optetrak® Total Knee System – Molded Metal Back Tibial Component
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: February 28, 2003
Received: March 5, 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) 594-4639. 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 may be obtained 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 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® Optetrak® Total Knee System
Line Extension – Molded Metal-back Tibial Component
Special 510(k)

Indications for Use

510(k) Number: K030686

Device Name: Molded Metal-back Tibial Component

INDICATIONS

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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 K030686

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes or Over the Counter Use No