K071738

Exactech®

AUG 15 2007

FAX 352-378-2617

510(k) Summary

Company: Exactech, Inc

Establishment Registration: 1038671

Date: June 25, 2007

Contact Person: Amnon Talmor, Regulatory Affairs Specialist

Proprietary Name: Exactech Optetrak® Proximal Tibial Spacer

Common Name: Tibial Knee Implant

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi constrained cemented prosthesis (21 CFR 888.3560, Class II, Product Code JWH)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

Device Name	510(k)/Product Code
Exactech Cruciate Retaining Cemented Tibial Components	#K932776/JWH
Exactech Optetrak® Total Knee System Tibial Component	#K933610/JWH
Exactech Porous Coated Finned Tibial Tray Component	#K936079/JWH
Exactech Optetrak® Constrained Condylar Knee for Cemented Use	#K954208/JWH
Exactech Optetrak® Size 0 and 1 Delta Line Extension	#K011976/JWH
Exactech Optetrak® Total Knee System Offset Tibial Tray	#K023186/JWH
Optetrak® Total Knee System HI-FLEX Posterior-Stabilized Tibial Insert Components	#K033883/JWH

Device Description

The proposed Exactech Optetrak® Proximal Tibial Spacer (PTS) is a titanium alloy spacer that assembles with the Optetrak® Tibial Tray and the Optetrak® Tibial Insert prostheses to replace the correct amount of joint space. This allows a combined tibial insert/tibial tray thickness comparable to the thickness provided by larger tibial inserts, while maintaining the function and performance of the predicate Optetrak Knee tibial insert/tibial tray assembly. The proposed Optetrak PTS is intended to take the place of inserts larger than 15mm by mating with the thinner inserts (ranging from 9mm to 15mm) to achieve the same total thickness.

Indications for Use

The OPTETRAK® Comprehensive 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.

The OPTETRAK® Comprehensive 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, patients with either mental or neuromuscular disorders that do not allow control of the knee joint, and patients whose weight, age, or activity level might cause extreme loads and early failure of the system.

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Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use.** Exactech Optetrak® PTS and predicate devices are intended for use in total knee joint replacement and have identical indications for use.
- **Materials.** Exactech Optetrak® PTS and predicate devices are composed of equivalent materials conforming to recognized industry standards for permanent implants.
- **Dimensions.** Exactech Optetrak® PTS and predicate device components are available in equivalent size ranges and have matching mating geometries.
- **Sterilization processes.** Exactech Optetrak® PTS and predicate devices are sterilized using equivalent sterilization processes conforming to recognized industry standards.
- **Performance specifications.** Exactech Optetrak® PTS and predicate devices conform to recognized performance standards for total knee replacement devices. The performance specifications for the Exactech Optetrak® PTS are equivalent to the predicates.

Summary of Non-Clinical Performance Data

Mechanical tests and engineering analyses were conducted to demonstrate the safety and effectiveness of the Exactech Optetrak® PTS and support the claim of substantial equivalence to the predicates listed above.

Substantial Equivalence Conclusion

Results from mechanical tests and engineering analyses provided within this 510(k) demonstrate that the Exactech Optetrak® PTS are substantially equivalent to the identified predicate devices. That is, the proposed device is as safe and effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Exactech, Inc.
% Mr. Amnon Talmor
Regulatory Affairs Specialist
2320 N. W. 66th Ct.
Gainesville, FL 32608

AUG 15 2007

Re: K071738
Trade/Device Name: Exactech Optetrak® Proximal Tibial Spacer
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis
Regulatory Class: Class II
Product Codes: JWH
Dated: June 25, 2007
Received: June 26, 2007

Dear Mr. Talmor:

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 (240) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 DGRND

Exactech®, Inc.

Indications for Use

510(k) Number (if known): K071738

Device Name: Exactech Optetrak® Proximal Tibial Spacer

INDICATIONS FOR USE:

The OPTETRAK® Comprehensive 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.

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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 General, Restorative, and Neurological Devices

510(k) Number K071738