Exactech® Optetrak Logic® Porous Femoral Component
Traditional 510(k) – 510(k) Summary of Safety and Effectiveness

JUL 30 2014

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

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FDA Establishment Number 1038671

Contact: Patrick Hughes
Senior Regulatory Affairs Specialist

Date: June 30, 2014

Trade or Proprietary or Model Name(s):
Exactech® Optetrak Logic® Porous Femoral Component

Common Name:
Femoral Knee Prosthesis

Classification Name:
21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; Class II

21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis; Class II

Device Code: JWH, MBH

Information on devices to which substantial equivalence is claimed:

510(k)	Trade or Proprietary or Model Name	Manufacturer
K123687	Optetrak Logic Porous Femoral Components	Exactech, Inc
K062654	Sigma CR Porocoat® Femoral Components	DePuy

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. In the USA, the OPTETRAK Comprehensive Knee Systems are indicated for cemented use only, except for the OPTETRAK Logic PS and CR Porous Femoral Components, which are indicated for cemented or cementless use.

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Device Description:
Subject Optetrak Logic Porous Femoral Component devices are the same devices as Optetrak Logic Porous Femoral Components cleared per K123687. The purpose of this submission is to expand the indications for use for these devices to provide surgeons with the option for using them without bone cement, as with predicate devices cleared per 510(k) submission K062654.

Both predicate and proposed devices share the following similarities:

- the same intended use
- the same materials
- the same basic fundamental scientific technology
- the same materials and processes used for packaging and sterilization

Summary of Testing:

- Porosity, pore size, and coating thickness characterization per ASTM F1854-09
- Chemical composition and material microstructure analysis

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Optetrak Logic Porous Femoral Component 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 Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2014

Exactech, Incorporated
Mr. Patrick Hughes
Senior Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K140302
Trade/Device Name: Exactech® Optetrak Logic® Porous Femoral Component
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: July 2, 2014
Received: July 7, 2014

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optetrak Logic® Porous Femoral Component
Traditional 510(k) – Indications for Use

510(k) Number: K140302

Device Name: Exactech® Optetrak Logic® Porous Femoral Component

INDICATIONS

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. In the USA, the OPTETRAK Comprehensive Knee Systems are indicated for cemented use only, except for the OPTETRAK Logic PS and CR Porous Femoral Components, which are indicated for cemented or cementless use.

Prescription Use ___X___ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices