



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 29, 2015

Exactech, Inc.
Patrick Hughes
Senior Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K150890
Trade/Device Name: Exactech® Optetrak Logic® CC
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-
Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 30, 2015
Received: April 2, 2015

Dear Patrick 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" (21 CFR 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K150890

Device Name

Exactech® Optetrak Logic® CC

Indications for Use (Describe)

The Exactech® Optetrak Logic® CC is 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 Exactech® Optetrak Logic® CC is indicated for cemented use only.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Exactech® Optetrak Logic® CC
Traditional 510(k) – 510(k) Summary of Safety and Effectiveness

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

Phone: (352) 377-1140
 Fax: (352) 378-2617

FDA Establishment Number 1038671

Contact: Patrick Hughes
 Senior Regulatory Affairs Specialist

Date: March 30, 2015

Trade or Proprietary or Model Name(s):
 Exactech® Optetrak Logic® CC

Common Name:
 Cemented Total Knee Prosthesis

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

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K954208	Optetrak CC	Exactech, Inc
K093360	Optetrak Logic	Exactech, Inc
K933610	Optetrak Trapezoidal Trays	Exactech, Inc.
K012251	Optetrak Stem Extensions	Exactech, Inc

Indications for Use:

The Optetrak Logic CC Total Knee System is 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 Logic CC Total Knee System is indicated for cemented use only.

Exactech® Optetrak Logic® CC
Traditional 510(k) – 510(k) Summary of Safety and Effectiveness

Device Description:

Optetrak Logic CC is a cemented total knee prosthesis system that provides femoral components, tibial inserts, stems, augments, and surgical instrumentation for use in primary and revision total knee arthroplasty. Like corresponding predicate Optetrak CC system femoral components and tibial inserts, Optetrak Logic CC femoral components and tibial inserts are constrained condylar prostheses featuring an increased level of constraint compared to other Optetrak and Optetrak Logic knee system devices. Optetrak Logic CC also provides various stem extensions and augment blocks surgeons can use to address bone defects and bone loss.

Testing Description:

This submission includes references to the following mechanical testing:

- Constraint testing
- Stem extension fatigue testing

Substantial Equivalence Conclusion:

Results of engineering studies referenced in this 510(k) submission demonstrate proposed Optetrak Logic CC Total Knee System devices are substantially equivalent to cited cleared predicate Optetrak devices.