



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

Total Joint Orthopedics, Incorporated
Mr. Chris Weaber
Manufacturing Development Engineer
1567 East Stratford Avenue
Salt Lake City, Utah 84106

November 13, 2015

Re: K153075

Trade/Device Name: Klassic™ Knee System

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: October 22, 2015

Received: October 26, 2015

Dear Mr. Weaber:

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 Parts 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,

Mark N. Melkerson -S

Mark N. 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)

K153075

Device Name

Klassic™ Knee System

Indications for Use (Describe)

The Klassic™ Knee System is intended for prosthetic replacement with the use of bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis
- Patients with failed previous surgery where pain, deformity, or dysfunction persists
- Correctable varus-valgus deformity and moderate flexion contracture
- Revision of a previously failed knee arthroplasty
- Patients who require a total knee replacement

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

5. 510(k) Summary

Manufacturer: Total Joint Orthopedics, Inc.
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Phone: 801.486.6070
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Contact: Mr. Chris Weaber
Manufacturing Development Engineer

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1331 H Street, NW, 12th Floor
Washington, DC 20005
Phone: 202.552.5800
Fax: 202.552.5798

Date Prepared: October 22, 2015

Device Trade Name: Klassic™ Knee System

Device Common Name: Total knee replacement system

Classification: 21 CFR 888.3560 – Knee joint patellofemorotibial
polymer/metal/polymer semi-constrained cemented

Class II

Product Code: JWH

Indications for Use:

The Klassic™ Knee System is intended for prosthetic replacement with the use of bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
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- Patients who require a total knee replacement

Device Description:

The Klassic™ Knee System is a cemented total knee joint replacement system comprised of modular components with varying sizes available for each component. The purpose of

this Special 510(k) is to add 18mm Ultra-PS and 18mm CR/Congruent tibial inserts to the Klasic™ Knee System. These components are manufactured from ultrahigh molecular weight polyethylene and each is available in 6 sizes.

Predicate Devices:

The modified Klasic™ Knee System is substantially equivalent to the predicate Klasic™ Knee System (K112906) with respect to indications, design, and function. The information summarized in the Design Control Activities Summary demonstrates that the 18mm Ultra-PS and 18mm CR/Congruent tibial insert met the pre-determined acceptance criteria for the verification activities.

Substantial Equivalence:

Engineering analyses were performed on the 18mm Ultra-PS and 18mm CR/Congruent tibial inserts and the previously cleared tibial inserts to evaluate their resistance to modular disassembly and stability characteristics. The results of these analyses indicate that the 18mm Ultra-PS and 18mm CR/Congruent tibial inserts are substantially equivalent to the predicate components.