



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

New Era Orthopedics, LLC
% Mr. Terry Powell, Sr.
Project Manager
M. Squared Associates, Inc.
575 Eight Avenue Suite 1212
New York, New York 10018

December 5, 2014

Re: K142388

Trade/Device Name: NEO Total 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 30, 2014

Received: November 3, 2014

Dear Mr. Powell:

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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use Statement

510(k) Number: K142388

Device Name: NEO Total Knee System

Indications for Use:

The NEO Total Knee System components are indicated for use in skeletally mature individuals, with severe knee pain and disability, undergoing surgery for total knee replacement due to:

- Osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, moderate deformities and femoral condyle osteonecrosis.
- Failed osteotomies, failed partial knee replacement, or failed total knee replacement whose age, weight and activity level are compatible with an adequate long-term result.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.

The cruciate retaining (CR) femur with CR tibial insert is for use when the posterior cruciate ligament (PCL) is intact. The CR femur with UC tibial inserts is for use when the PCL is sacrificed. The posteriorly stabilized (PS) femur with PS tibial insert is for use when the PCL is sacrificed.

The NEO Total Knee System components are indicated for use only with cement and are single use devices.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NEO Total Knee System 510(k) Summary – K142388

Device Proprietary Name: NEO Total Knee System

Common Name: Total Knee System

Classification regulation: 888.3560

Device Class: Class II

Product Codes: JWH

Submitter's Name: New Era Orthopedics, LLC
Address: 1214 Research Boulevard, Suite 1019
Hummelstown, PA 17036

Contact Person: Craig Corrance
Telephone Number: 717 585 6785
Fax Number: 407 386 3348

Date Summary Prepared: August 25, 2014

Purpose of Submission

To obtain 510(k)s under the name of the New Era Orthopedics, LLC for the same NEO Total Knee System, with minor dimensional changes, as previously cleared in 510(k)s #K120313, K122500, and K131368.

Device Description:

The NEO Total Knee System includes:

- Cruciate retaining (CR) Femoral Components and Posteriorly stabilized (PS) Femoral Components in right and left configurations in sizes 1 to 10, manufactured from Cast CoCr.
- Tibial Trays manufactured from titanium alloy in sizes 1 – 10.
- Tibial Inserts in cruciate retaining (CR), ultracongruent (UC), and posteriorly stabilized (PS) designs, manufactured from standard ultrahigh molecular weight polyethylene, in sizes A to E and in thicknesses 6 to 21 mm (total thickness with tibial tray is 9 to 24 mm).
- Patellar Components in diameters of 26 to 41 mm and in thicknesses of 8, 9 or 10 mm, manufactured from standard ultrahigh molecular weight polyethylene.

The NEO Total Knee System is designed with the potential to have an active clinical flexion of 150°.

Intended Use:

The NEO Total Knee System components are indicated for use in skeletally mature individuals, with severe knee pain and disability, undergoing surgery for total knee

NEO Total Knee System 510(k) Summary – K142388

replacement due to:

- Osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, moderate deformities and femoral condyle osteonecrosis.
- Failed osteotomies, failed partial knee replacement, or failed total knee replacement whose age, weight and activity level are compatible with an adequate long-term result.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.

The cruciate retaining (CR) femoral component with CR tibial insert is for use when the posterior cruciate ligament (PCL) is intact. The CR femoral component with UC tibial insert is for use when the PCL is sacrificed. The posteriorly stabilized (PS) femoral component with PS tibial insert is for use when the PCL is sacrificed.

The NEO Total Knee System components are indicated for use only with cement and are single use devices.

Predicate Devices:

The predicate devices are:

| Trade/Proprietary Name | 510(K) # | Clearance Date |
|---|-----------------|-----------------------|
| NEO CR Knee System | K120313 | 04-20-2012 |
| NEO PS Knee | K122500 | 05-03-2013 |
| NEO Total Knee System – Line Extension (UC inserts) | K131368 | 10-03-2013 |

Technological Characteristics:

The NEO Total Knee System has the same indications for use, is manufactured from the same materials using the same methods, and has the same design features as the predicate knee systems, and uses traditional sterilization methods. The NEO Total Knee System described in the subject 510(k) is the same knee system, with minor dimensional modifications, previously cleared for marketing in 510(k) #K120313, K122500, and K131368.

Performance Testing:

The NEO Total Knee System has been evaluated for tibial tray fatigue strength, insert locking mechanism strength, tibial post strength (for PS design), femorotibial range of motion, femorotibial range of constraint, patellofemoral range of constraint, femorotibial contact areas/contact stress, and patellofemoral contact area and contact stress.

NEO Total Knee System 510(k) Summary - K142388

Substantial Equivalence Information:

The NEO Total Knee System is the same, except for minor dimensional changes, as the predicate NEO Total Knee System, and is therefore substantially equivalent.