K123339

NovoSource

510(k) Summary

APR 1 1 2013

Applicant/Sponsor:	**NovoSource, Inc.** **714 East Monument Ave. Suite 219** **Dayton, OH, 45402** **937-531-6591**
Contact Person:	**David Letteri** **VP, Quality and Regulatory at NovoSource, Inc.** **NovoSource, Inc.** **714 East Monument Ave. Suite 219** **Dayton, OH, 45402** **937-531-6591**
Date Prepared:	**October 30, 2012**

DEVICE INFORMATION

Proposed Trade Name:	**NovoKnee Total Knee System**
Common Name:	**Semi-constrained total knee prosthesis**
Classification Name:	**Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel/87 as a Class II device.**
Device Product Code:	**JWH**
Predicate Device:	**U2 Total Knee System (K051640)**

Device Description:

The NovoKnee Total Knee System is of the fixed bearing type with a posterior stabilized design. It is a Patellofemorotibia, polymer/metal/polymer, semi-constrained, cemented knee prosthesis, that consists of a femoral component, tibial insert, tibial tray and patellar component. The femoral component articulates with the tibial insert component. The underside of the tibial insert component is flat and "snaps" into the tibial baseplate component. Each femoral component has the same intercondylar distance and radius of curvature. Each tibial insert component is complimentarily shaped to conform to the femoral components. This allows any size femoral component to be matched with any size tibial component. The dome shape of each UHMWPE patellar component provides excellent contact with the femoral component and evenly distributes stresses. The dome and sombrero shape of each UHMWPE patellar component provides contact with the femoral component.

Intended Use:

Total knee arthroplasty

Indications for Use:

The NovoKnee Total Knee System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. The NovoKnee Total Knee System may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. The NovoKnee Total Knee System is designed for cemented use only.

Summary of Technological Characteristics

The NovoKnee Total Knee System has the same intended use and indications as the U2 Total Knee system. The NovoKnee Total Knee System is manufactured from the same, or equivalent, materials as the U2 Total Knee system. The range of sizes available for the NovoKnee Total Knee System is the same as the range of sizes of the U2 Total Knee system. The NovoKnee Total Knee System design is substantially similar to the U2 Total Knee system design. Based on these similarities, NovoSource believes that the NovoKnee Total Knee System is substantially equivalent to the U2 Total Knee system.

Performance Testing

The NovoKnee Total Knee System was tested for fatigue performance of the tibial tray, interlock mechanism strength (between the tibial tray and tibial insert), shear fatigue strength of the tibial insert post, femoral/tibial insert contact pressures and areas, lateral subluxation of patellar component, and range of motion performance. Test results indicate that the NovoKnee Total Knee System is equivalent to the U2 Total Knee System and is capable of withstanding expected in vivo loading without failure.

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

NovoSource, Incorporated
% IMDS Corporation
Mr. James Pinkston
Regulatory Consultant
124 South 600 West
Logan, Utah 84321

Letter dated: April 11, 2013

Re: K123339
Trade/Device Name: NovoKnee 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: January 28, 2013
Received: March 13, 2013

Dear Mr. Pinkston:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

Indications for Use

510(k) Number (if known): K123339

Device Name: **NovoKnee Total Knee System**

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices