Pipeline Knee System
510(k) Summary: K123692

MAY 2 4 2013

Device Proprietary Name:	Pipeline Knee System
Common Name:	Total Knee System
Classification regulation:	888.3560
Device Class:	Class II
Product Codes:	JWH (cemented knees)
Submitter's Name:	Pipeline Orthopedics
Address:	3 Wing Drive, Suite 102, Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810
Date Summary Prepared:	May 23, 2013

Device Description

The Pipeline Knee System is a patellofemorotibial polymer/metal/polymer semi-constrained cemented knee joint prosthesis. The system includes femoral components, tibial trays, biomimetic cruciate retaining (CR) tibial inserts, patellar components, and associated instrumentation. The tibial trays are manufactured from highly crosslinked vitamin E polyethylene. The patellar components are manufactured from vitamin E polyethylene. The CR inserts are designed for use when the posterior cruciate ligament is intact.

The Pipeline Total Knee System femoral component, when used with the Pipeline Knee System articular surfaces, is designed to achieve flexion at high angles and provide a clinical ROM up to 150 degrees.

Purpose of Submission:

The Pipeline Knee System subject of this 510(k) represents an evolution of the component designs and a line extension to the original Pipeline Knee System cleared by the FDA on March 20, 2012 via 510(k) #K113122.

Intended Use:

The Pipeline Knee System is indicated for skeletally mature patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis,
- Collagen disorders, and/or avascular necrosis of the femoral condyle,
- Post-traumatic loss of joint configuration, particularly when there is

patellofemoral erosion, dysfunction or prior patellectomy,
- Moderate valgus, varus, or flexion deformities,
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot otherwise be obtained at the time of surgery.

Pipeline Knee System components are indicated for use only with cement, and are single use devices.

Predicate Devices:

Trade/Proprietary Name	Manufacturer	510(K) #
Pipeline CR Total Knee System	Pipeline	K113122
Triathlon Knee Systems	Stryker	K040267
Evolution MP (medial pivot) Total Knee Systems	Wright Medical Technology	K093552
Journey II Knee System: CR Knee System, Deep Dished Articular Insert, BCS Knee System	Smith & Nephew	K121443 K113482 K111711
Persona Personalized Knee (CR, UC, PS Inserts)	Zimmer	K113369
Corin Trinity Acetabular System ECIMA Liners	Corin USA	K111481
Vanguard Patellar Components	Biomet	K040770
iTotal Cruciate Retaining Knee Replacement System with iPoly XE Tibial Inserts and Patellae	ConforMIS Inc.	K122870
Natural Knee II Durasul Tibial Insert and Patella	Sulzer Orthopedics	K000235

Technological Characteristics/Substantial Equivalence:
The Pipeline Knee System is similar to legally marketed devices listed previously in that they share the same indications for use, are manufactured from the same or similar materials, incorporate similar design/technological characteristics, and have performance characteristics adequate to withstand anticipated physiologic loading.

Performance Data
The Pipeline Knee System has been evaluated through non-clinical performance testing for tibial tray fatigue strength, insert locking mechanism strength, femorotibial range of motion, femorotibial range of constraint, patellofemoral range of constraint, femorotibial contact areas/contact stress, and patellofemoral contact area and contact

stress, and wear simulation. In addition, testing of the following properties was provided to support the substantial equivalence of the highly-crosslinked Vitamin E polyethylene: tensile strength, yield strength, elongation, density, crystallinity, wear resistance and particle size characterization, free radical concentration, thermal properties, impact strength, small punch strength, oxidation resistance, trans vinylene index, and biocompatibility testing.

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

May 24, 2013

Pipeline Orthopedics, LLC
% M Squared Associates, Incorporated
Ms. Terry Sheridan Powell
901 King Street, Suite 102
Alexandria, Virginia 22314

Re: K123692
Trade/Device Name: Pipeline Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: April 22, 2013
Received: April 23, 2013

Dear Ms. 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 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,

For 

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: ~~To be assigned~~ K123692

Device Name: Pipeline Knee System

Indications for Use: The Pipeline Knee System is indicated for skeletally mature patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis,
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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-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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