510(k) Summary

JUL 0 1 2013

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

1.1. Device Name and Classification

Device Trade Name:	Pipeline Total Hip System
Device Common Name:	Artificial Total Hip Replacement System Components
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
Advisory Panel:	Orthopedic

1.2. Address and Registration

Submitter's Name:	Pipeline Biomedical Products, LLC
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:	February 11, 2013
Establishment Registration Number:	3009701876

1.3. Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject Pipeline Total Hip System Line Extension is substantially equivalent to the predicate devices shown in the following table.

Table 1: Predicate Devices

Device Name	Company	510(k) Number	Clearance Date
Pipeline Total Hip System	Pipeline Orthopedics	K112802	3/9/2012
PBP Total Hip System	Pipeline Biomedical Products	K122802	12/11/2012
Synergy Hip System	Smith & Nephew Orthopedics	K061066	7/14/2006
Trident Screw Hole Plugs	Stryker Orthopaedics (formerly Howmedica Osteonics Corp.)	K022799	11/21/2002

1.4. Device Description

The predicate Pipeline Total Hip System (K112802) and PBP Total Hip System (K122802) are artificial hip replacement systems that include femoral stems (titanium alloy and CP titanium), femoral heads (cobalt chromium or alumina ceramic), acetabular shells (titanium alloy, porous structured technology (PST™)), acetabular liners (ultrahigh molecular weight polyethylene, standard and highly crosslinked Vitamin E), acetabular bone screws (titanium alloy) and dome hole covers (titanium alloy) for the holes in the acetabular shells. This subject 510k adds the following components to the existing hip systems:

- A smaller, size 1 femoral stem;
- The option of hip stems (all sizes) with 3 tantalum beads, to allow the surgeon to perform radiostereometric analysis(RSA) to measure implant migration; and
- The option of acetabular screw hole occluders provided either separately (for assembly by the surgeon), or pre-assembled to the acetabular shells.

1.5. Intended Use

PIPELINE Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PIPELINE Tapered Femoral Stem and PIPELINE PST™ Acetabular Shell are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PIPELINE PST™ Acetabular Shell with HA is intended for cementless fixation. The porous structured surface with HA provides biological fixation.

1.6. Comparison of Technological Characteristics

The Pipeline Total Hip System described in this 510k has the same indications for use as the predicate Pipeline Total Hip System. The additional Pipeline Total Hip System components described in this 510k have similar designs to one or more of the identified predicate devices, and are manufactured from the same materials as one or more of the predicate device systems, and/or from materials that comply with recognized implantable materials standards. The components are packaged and sterilized using the

same processes as one or more of the predicate devices. The subject Pipeline Total Hip System components are therefore substantially equivalent to the predicates based on comparisons of intended use, design features and technological characteristics, materials, and sterilization/packaging methods.

1.7. Performance Testing

The following performance tests and engineering analyses were provided to demonstrate substantial equivalence:

- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components, and Engineering Analysis was conducted to determine satisfactory distal boundary for the plasma spray coating.
- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.

1.8. Conclusions

The subject Pipeline Total Hip System components share the same indications for use as the predicate Pipeline hip system, and a comparison of technological characteristics supported by performance testing demonstrates the Substantial Equivalence of the subject Pipeline Total Hip System components to one or more of the identified predicate devices.

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

July 1, 2013

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

Re: K130353
Trade/Device Name: Pipeline Total Hip System – Line Extension
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: May 30, 2013
Received: June 3, 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,

Erin L. Keith

For

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K130353

Device Name: Pipeline Total Hip System – Line Extension

Indications for Use:

PIPELINE Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PIPELINE Tapered Femoral Stem and PIPELINE PST™ Acetabular Shell are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PIPELINE PST™ Acetabular Shell with HA is intended for cementless fixation. The porous structured surface with HA provides biological fixation.

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

Elizabeth L. Frank -S

Division of Orthopedic Devices