510(k) Summary – 510(k) #K132626

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

Device Name and Classification

Device Trade Name:	Pipeline Total Hip System – Line Extension
Device Common Name:	Artificial Total Hip Replacement
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 OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis) OQI (hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented) MEH (prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate)
Advisory Panel:	Orthopedic

Address and Registration

Submitter's Name:	Pipeline Biotechnology, LLC
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Jaclyn C. Docs
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810
Date Summary Prepared:	August 21, 2013
Establishment Registration Number:	Not registered yet

Purpose of Submission

This Special 510(k) addresses an administrative line extension to the subject total hip system (510(k) #K122158), and introduces hip system components that have already been determined substantially equivalent by FDA in 510(k) #K130353 for the designated indications for use under the name of another subsidiary of the parent holding company.

Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject size #1 hip stems, RSA hip stems, and acetabular shell screw hole occluder submitted in this

510(k) under the name of Pipeline Biotechnology, are identical, and therefore substantially equivalent to, the same devices cleared under the name of Pipeline Biomedical Holdings' subsidiary, Pipeline Orthopedics, in predicate 510(k) number K130353.

Device Description

This 510(k) addresses the addition of the following components (already cleared under 510(k) #K130353) to the subject hip system:

- A size 1 femoral stem;
- Hip stems (all sizes, 1-12) with the option of 3 tantalum beads, to allow the surgeon to perform radiostereometric analysis(RSA) to measure implant migration; and
- Optional acetabular screw hole occluders provided either separately (for assembly by the surgeon), or pre-assembled to the acetabular shells.

These components are compatible with the total hip system determined substantially equivalent as the Pipeline Total Hip System in 510(k) #K112802 and K131237 and as the PBP Total Hip System in 510(k) #K122158.

Intended Use

The 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.

Comparison of Technological Characteristics

The components described in this 510(k) are identical to the same components determined substantially equivalent in predicate 510(k) #K130353 in all respects except for the Pipeline Biomedical Holdings subsidiary name assigned to the 510(k). There is no difference in intended use, materials, design features, component sizing, or manufacturing methods.

Summary of Nonclinical Testing

The subject devices are identical in every aspect to the predicate devices cleared through 510(k) #K130353. The only change being made is to the Pipeline Biomedical Holdings subsidiary name assigned to the 510(k). Therefore, no additional testing was conducted.

Conclusions

The subject components share the same indications for use as the predicate components, and feature the identical design, materials, sizing, manufacturing/packaging/sterilization methods and performance characteristics, and are therefore substantially equivalent.

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

October 16, 2013

Pipeline Biotechnology, LLC
% Ms. Terry Sheridan Powell
M Squared Associates Incorporated, Consultants for Pipeline Biotechnology, LLC.
575 Eighth Avenue, Suite 1212
New York, New York 10018

Re: K132626
Trade/Device Name: Pipeline Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI, OQG, OQH, LZO, OQI, MEH
Dated: August 21, 2013
Received: August 22, 2013

Dear Ms. Powell:

This letter corrects our substantially equivalent letter of September 19, 2013.

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 Erin I. Keith

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

Enclosure

6 Indication for Use Statement

510(k) Number (if known): K132626 to be assigned

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.

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

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)

Elizabeth L. Frank -S

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