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

September 6, 2016

Signature Orthopaedics Pty Ltd.
Dr. Declan Brazil
Managing Director
7 Sirius Road
Lane Cove, NSW 2066
AUSTRALIA

Re: K160159
Trade/Device Name: Active-X 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, MBH
Dated: August 9, 2016
Received: August 12, 2016

Dear Dr. Brazil:

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 Parts 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,

Mark N. Melkerson -S

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

Enclosure

1 INDICATIONS FOR USE STATEMENT

510(k) Number (if Known): K160159

Device Name: Active-X Total Knee System

Indications For Use:

The patient should be skeletally mature to receive a knee replacement. Patients should have adequate bone stock and size to support and accept the prosthesis.
The patient's need for knee replacement should be due to one or more of the following conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Functional deformity such as varus, valgus or flexion deformities.
- Revision procedures where other treatments or devices have failed.
- Fractures that are unmanageable using other techniques.

The Active-X Knee replacement system is indicated for cemented fixation with bone cement (PMMA) only.

Prescription Use: Yes
(Part 29 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: No
(Part 29 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)

2 510(K) SUMMARY

Manufacturer: Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Australia

Device Trade Name: Active-X Total Knee System

Common Name: Total Knee Prosthesis

Contact: Dr. Declan Brazil
Managing Director of Signature Orthopaedics

Prepared By: Signature Orthopaedics Pty Ltd
7 Sirius Road
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Australia
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Date Prepared: January 20th, 2015

Classification: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (JWH, 21CFR 888.3560)

Predicate Devices: Substantial equivalence to the following device is claimed:

- Primary Predicate: dj Orthopedics Alaron Surgical Active Knee® System (K021740)
- Reference Predicate: Smith & Nephew Genesis II Knee System Inlay Patella Component (K032683)

Device Description:

The Active-X Knee system is a modular knee system consisting of a femoral component, a standard, ultracongruent and ultracongruent+ meniscal insert (anterior lip), a patella and a tibial baseplate. The femoral component and tibial baseplate components are manufactured from cast cobalt chromium alloy and are intended for use with bone cement. All variants of the meniscal insert and patella are manufactured from UHMWPE.

Indications for Use:

The patient should be skeletally mature to receive a knee replacement. Patients should have adequate bone stock and size to support and accept the prosthesis.
The patient's need for knee replacement should be due to one or more of the following

conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Functional deformity such as varus, valgus or flexion deformities.
- Revision procedures where other treatments or devices have failed.
- Fractures that are unmanageable using other techniques.

The Active-X Knee replacement system is indicated for cemented fixation with bone cement (PMMA) only.

Performance Testing:

Engineering evaluations were performed to demonstrate equivalent performance between the Active-X Knee System and the dj Orthopedics Alaron Surgical Active Knee® System (K021740). The Active-X Knee System is identical to the dj Orthopaedics Alaron Surgical Active Knee System (K021740) with the addition of the ultracongruent+ meniscal insert and inlay patella. Engineering evaluations have shown that the ultracongruent+ meniscal insert and inlay patella perform equivalently to the remainder of the Active-X Knee System and the dj Orthopaedics Alaron Surgical Active Knee System (K021740); therefore, further device testing is not required. The following testing has been omitted on the basis of the engineering evaluations:

- Range of motion analysis
- Modular component connection strength testing
- Component Contact Area and Stress Testing
- Component Constraint Testing
- Wear Testing
- Cement fixation testing

Substantial Equivalence:

The Active-X Total Knee system devices have the same intended use, indications for use, materials and design to the Alaron Surgical Active Knee® System (K021740), excluding the ultracongruent+ meniscal insert and the inlay patella geometry. The ultracongruent+ meniscal insert features an increased anterior lip compared to the Alaron Surgical Active Knee ultracongruent meniscal to further compensate for a deficient PCL. The inlay patella has similar design features to the Genesis II Total Knee System Inlay Patella Component (K032683). The materials, function, intended use, and fundamental scientific technology remain the same. Non-clinical testing results support the substantial equivalence claim.