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

Signature Orthopaedics Pty Ltd. July 17, 2017
Declan Brazil
Managing Director
7 Sirius Road
Lane Cove, NSW 2066
Australia

Re: K170613
Trade/Device Name: Genius 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: June 6, 2017
Received: June 8, 2017

Dear Declan 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 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 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" (21 CFR 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

Signature Orthopaedics Pty Ltd

1 INDICATIONS FOR USE STATEMENT

510(k) Number (if Known): K170613

Device Name: Genius 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 Genius 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: Genius Total Knee System

Common Name: Total Knee Prosthesis

Contact:
Dr. Declan Brazil
Managing Director of Signature Orthopaedics

Prepared By:
Signature Orthopaedics Pty Ltd
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Australia
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Date Prepared: February 23rd, 2017

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:

- Johnson & Johnson Professional Inc. Darwin Knee System (K943462) now Depuy PFC Sigma Knee System
- Signature Orthopaedics Active-X Knee System (K160159)
- Biomet Vanguard Complete Knee System (K113550)
- DePuy AMK System (K864671)
- New Era Orthopaedics NEO Total Knee System (K142388)

Device Description:

The Genius Knee system is a modular knee system consisting of a femoral component, meniscal insert, 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. The femoral component is available with femoral pegs, or as modular peg variant. The modular femoral peg is manufactured from wrought cobalt chromium alloy. The femoral component and meniscal inserts are available as posterior stabilised or cruciate retaining variants. Cruciate retaining meniscal inserts are available as standard or ultracongruent designs. 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 Genius Knee replacement system is indicated for cemented fixation with bone cement (PMMA) only.

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Genius Knee system is adequate for anticipated in-vivo use. Non-clinical testing carried out on the Genius Knee system included:

- Range of motion analysis
- Modular component interlock strength testing
- Component contact area and stress testing
- Component constraint testing
- Tibial plate fatigue testing
- UHMWPE tibial post strength analysis
- Modular component assembly testing
- Modular component disassembly testing
- Endotoxin (LAL) Testing

Substantial Equivalence:

The Genius Knee System has the same intended use, indications for use, materials and similar design as the DePuy PFC Sigma Knee System (K943462), Signature Orthopaedics Active-X Knee System (K160159), Biomet Vanguard Complete Knee System (K113550), DePuy AMK System (K864671) and New Era Orthopaedics NEO Total Knee System (K142388). Non-clinical testing results support the substantial equivalence claim. The subject devices are expected to perform adequately during clinical use.

Comparison of technological characteristics

Reconstructive total knee joint replacement is the technological principle for both the subject devices and the predicate devices. At a high level, the subject and predicate devices are based on the following same technological elements:

- The indication for use of the subject devices is the same as one or more of the predicate devices
- The intended surgery sites of the subject devices matches the intended surgery sites of the predicates
- The subject devices are manufactured from the same materials at least one of the predicates for femoral, meniscal, tibial tray and patella components
- The subject devices are for use with cemented fixation which is in line with at least one of the predicates
- The range of sizes of the subject devices are within the range of sizes of at least one of the predicates for femoral, meniscal, tibial tray and patella components
- The modular locking mechanisms are the same as at least one of the predicates
- The subject device is available in posterior stabilized and cruciate retaining variants which is the same as at least one of the predicates
- The subject device is available with a highly congruent cruciate retaining meniscal insert which is the same as at least one of the predicates
- The subject device is fixed bearing which is the same as at least one of the predicates

The following technological differences exist between the subject and predicate devices:

- Some of the design features are different between the subject and predicate devices
- Some of the femoral variants of the subject device are not available with some of the predicates devices
- The metallic material used on at least one of the predicates differs to what is used in the subject devices
- The polymeric material used on at least one of the predicates differs slightly to what is used in the subject devices
- The modular locking mechanism of the tibial tray differs in at least one of the predicates