June 15, 2023

Xerxes Arthopedix LLC
H Kurtis Biggs
President
181 Eugenia Dr.
Naples, Florida 34108

Re: K231109
Trade/Device Name: Xerxes Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, KWZ
Dated: April 13, 2023
Received: April 19, 2023

Dear Dr. H Kurtis Biggs:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231109

Device Name
Xerxes Hip Stem

Indications for Use *(Describe)*

Xerxes Hip Stems, when used with cleared and compatible Signature Orthopaedics hip replacement components, are intended to replace a hip joint where bone stock is sufficient to support the implant. When a surgeon has selected prosthetic replacement as the preferred treatment, the devices are indicated for:

- Non-inflammatory degenerative joint disease including osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis
- Correction of functional deformity including congenital hip dysplasia
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head or neck fracture
- Failed previous hip surgery including internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement.

Xerxes Hip femoral stems are intended for cementless fixation only. The Xerxes Hip System is intended for use with Logical, World Acetabular System and Signature Orthopaedics' Femoral Heads.

Xerxes Hip when used with constrained liner components is indicated particularly for patients at high risk of hip dislocation due to history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(K) SUMMARY

Device Trade Name: Xerxes Hip Stem

Common Name: Cementless Hip Replacement Prosthesis

Contact: Dr. H. Kurtis Biggs
President, Xerxes Arthropedix LLC

Submitter: *Xerxes Arthropedix LLC*
181 Eugenia Dr., Naples, FL 34108
Phone: 239-313-0543
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Date Prepared: 15 June 2023

Classification: Class II as per 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Class II as per 21 CFR 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis

Product Codes: LZO, MEH, KWZ

Predicate Devices:

Primary Predicate

- Medacta International's MiniMAX Stem (K170845 & K192352)

Additional Predicate Device(s):

- Signature Orthopaedics' Spartan Hip Stem (K192883)
- Signature Orthopaedics' Everglade Hip Stem (K211505)
- Signature Orthopaedics' Origin™ Total Hip System (K121297)
- Signature Orthopaedics' Logical C-Series Acetabular Shell, Logical Constrained Liner, Logical Constrained Liner Collar, Logical 20º Hooded Acetabular Liner (K153131)

Device Description:

Xerxes™ Hip Stem is manufactured from forged titanium alloy (Ti6Al4V) as per ISO 5832-3 and ASTM F136. The Xerxes™ Hip Stem is an anatomical stem with a 5º anteversion neck and a 250 mm radius curvature on the stem body. The stem has three different surface and/or coating areas. The distal tip portion is colour anodised, polished, and rounded to aid in the insertion and avoiding distal interference. The remainder of the stem below its resection line is coated for cementless fixation. The middle portion of the stem is coated with a single layer of hydroxyapatite coating, as per ISO 13779-2 while the proximal portion is coated with an additional layer of titanium plasma spray as per ASTM F1580.

Indications for Use:

Xerxes™ Hip Stems, when used with cleared and compatible Signature Orthopaedics hip replacement components, are intended to replace a hip joint where bone stock is sufficient to

support the implant. When a surgeon has selected prosthetic replacement as the preferred treatment, the devices are indicated for:

- Non-inflammatory degenerative joint disease including osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis
- Correction of functional deformity including congenital hip dysplasia
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head or neck fracture
- Failed previous hip surgery including internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement

Xerxes™ Hip femoral stems are intended for cementless fixation only. The Xerxes™ Hip System is intended for use with Logical™, World™ Acetabular Systems and Signature Orthopaedics' Femoral Heads.

Xerxes™ Hip when used with constrained liner components is indicated particularly for patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

Summary of Technological Characteristics:

Hip arthroplasty is the technological principle for both the subject and the predicate devices. The subject and primary predicate devices are based on the same technological elements as listed below:

- The subject device is intended for cementless fixation which is the same intended use as the MiniMAX Stem.
- The indications for use of the subject device are the same as the MiniMAX Stem.
- The intended surgery sites of the subject device match the intended surgery sites of the MiniMAX Stem.
- The subject devices are manufactured from the same raw and coating materials as the MiniMAX Stem.
- The subject device has the same design features and size ranges as Medacta International's MiniMAX Stem.
- The subject device has the same 12/14 femoral head connection feature as the MiniMax Stem

The following are the technological differences between the subject device and the primary predicate devices:

- The subject device has a smaller anteversion angle neck design than the MiniMAX Stem

Further comparison of the subject device and additional predicate devices was made and found that:

- The subject device has the same 12/14 trunnion geometry as the Spartan and Everglade Stems.
- The subject device has the same surface finish on the taper connection as the Spartan and Everglade Stems.
- The subject device is compatible with the same femoral heads and associated acetabular components as the Spartan and Everglade Hip Stems.
- The subject device is manufactured and sterilised using the same methods as the Spartan and Everglade Stems.

Performance Data:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Xerxes Hip Stem is adequate for anticipated in-vivo use. No animal or clinical testing was required to support substantial equivalence. Non-clinical testing carried out included:

- Range of Motion testing as per ISO 21535
- Stem and Neck Fatigue FEA as per ASTM F2996
- Stem and Neck Fatigue Testing as per ISO 7206-4 and ISO 7206-6
- Pyrogenicity and Endotoxin Testing as per AAMI ST72

Conclusion:

Xerxes™ Stem is substantially equivalent to Medacta International's MiniMAX Stem (K170845 and K192352) since it has the same intended use, indications for use, material and similar design features. Non-clinical testing results support the substantial equivalence claim. Therefore, the subject devices are expected to perform adequately during clinical use.