December 3, 2021

Total Joint Othopedics, Inc.
Chris Weaber
Director of Research and Development
1567 E. Stratford Avenue
Salt Lake City, Utah 84106

Re: K213580
Trade/Device Name: Adapter Sleeve for BIOLOX® OPTION Femoral Head, +10.5mm head length
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, MBL, LPH, LWJ, OQG
Dated: November 10, 2021
Received: November 10, 2021

Dear Chris Weaber:

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, Ph.D.
Acting 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)*
K213580

Device Name
Adapter Sleeve for BIOLOX® OPTION Femoral Head, +10.5mm head length

Indications for Use *(Describe)*
The Klassic HD Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

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.

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510(k) Summary

Manufacturer: Total Joint Orthopedics, Inc.
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Phone: 801.486.6070
Fax: 801.486.6117

Contact: Mr. Chris Weaber
Director of Research and Development

Prepared By: MCRA, LLC
803 7th Street NW
Washington, DC 20001
Phone: 202.552.5800
Fax: 202.552.5798

Date Prepared: December 1st, 2021

Device Trade Name: Adapter Sleeve for BIOLOX® OPTION Femoral Head, +10.5mm head length

Common Name: Femoral Head Adapter Sleeve

Classifications: 21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

21 CFR 888.3358 - Hip joint metal/polymer/metal semi constrained porous-coated uncemented prosthesis

21 CFR 888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

Class II

Product Codes: LZO, MBL, LPH, LWJ, OQG

Indications for Use:
The Klassic HD® Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.

- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

Device Description:
The Klassic HD® Hip System employs prostheses designed to help surgeons restore hip joint biomechanics intra-operatively. The +10.5mm offset option for the Femoral Head Adapter Sleeves is a line extension to the currently available predicate adapter head offsets (K100445). The subject device is fabricated from Ti6Al4V per ASTM F136. The subject device is compatible with 32mm and 36mm BIOLOX® OPTION Ceramic Femoral Heads (K143407), and also compatible with the Klassic HD® Femoral Stems (K100445) and the Klassic Blade Femoral Stems (K151440 and K171962). The subject components are provided sterile, for single use, by prescription only.

Predicate Devices:
The modified Klassic HD® Hip System is substantially equivalent to the Klassic HD® Hip System (K180929, K143407, K100445) with respect to indications, design, materials, and function. The information summarized in the Design Control Activities Summary demonstrates that the modified Klassic HD® Hip System met the pre-determined acceptance criteria for the verification activities.

Comparison of Technological Characteristics:
The subject device features the same material (Ti6Al4V per ASTM F136), same intended use as a femoral head adapter, same femoral head and femoral stem taper interface design, similar geometry, same system compatibility, biocompatibility, and same gamma sterilization compared to the predicate Adapter Sleeves (K100445).

Discussion of Non-Clinical Testing/Performance Data:

Non-clinical testing and engineering analysis conducted to demonstrate substantial equivalence was as follows:

- Femoral Neck Fatigue testing per ISO 7206-6 of femoral stem with subject +10.5 adapter sleeve and femoral head
- Femoral Stem fatigue per ISO 7206-4 (via Engineering Analysis) of femoral stem with subject +10.5 adapter sleeve and femoral head
- Femoral head burst Strength and Post-fatigue Burst Strength per ISO 7206-10 of femoral head and +10.5mm subject adapter sleeve
- Femoral Head Pull-Off testing per ISO 7206-10 of femoral stem with +10.5 subject adapter sleeve and femoral head
- Femoral Head Torque disassembly testing per ISO 7206-13 of femoral stem with +10.5 subject adapter sleeve and femoral head

- Impingement per ASTM F2582-14 (via Engineering Analysis) of femoral stem, +10.5mm subject adapter sleeve, femoral head, acetabular insert and acetabular shell
- Range of Motion per ISO 21535-07 of femoral stem, +10.5mm subject adapter sleeve, femoral head, acetabular insert and acetabular shell

Additionally, the Klassic HD® Hip System is in compliance with LAL testing requirements for orthopedic implants per AAMI-ST72.

Conclusion:
Testing and engineering analyses showed that the subject components met the pre-determined acceptance criteria identified in the Design Control Activities, demonstrating that the subject component performs as safe and effective compared to the predicate components, and is substantially equivalent to the predicate.