



Total Joint Orthopedics, Inc.
Chris Weaber
Product Development, Regulatory Manager
1567 E. Stratford Avenue
Salt Lake City, Utah 84106

August 28, 2019

Re: K191399

Trade/Device Name: BIOLOX CONTOURA Ceramic Femoral Head
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, LPH, MBL, LWJ, OQG
Dated: July 29, 2019
Received: July 29, 2019

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,

FOR Vesa Vuniqui
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K191399

Device Name

BIOLOX CONTOURA® Ceramic Femoral Head

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Manufacturer: Total Joint Orthopedics, Inc.
1567 E. Stratford Avenue
Salt Lake City, UT 84106
Phone: 801.486.6070

Contact: Mr. Chris Weaber
Product Development, Regulatory Manager

Prepared By: MCRA, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: May 23, 2019

Device Trade Name: BIOLOX CONTOURA® Ceramic Femoral Head

Common Name: Ceramic Femoral Head

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

Class II

Product Codes: LZO, LPH, MBL, 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 purpose of this Special 510(k) is to add BIOLOX CONTOURA[®] Ceramic Femoral Heads in diameters of 28mm, 32mm, and 36mm, in various head offsets.

Predicate Devices:

The modified Klassic HD[®] Hip System is substantially equivalent to the predicate Klassic HD[®] Hip System (K100445 & K180929), and Klassic HD[®] Ceramic Femoral Heads (K143407) 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.

Substantial Equivalence:

The subject device underwent burst strength testing, burst fatigue testing, post-fatigue burst strength testing, pull-off testing, and torque disassembly testing. In addition, engineering analyses were performed to evaluate the impingement, range of motion and wear of BIOLOX CONTOURA[®] ceramic femoral heads. Testing and engineering analyses showed that the subject components met the pre-determined acceptance criteria identified in the Design Control Activities. Additionally, the Klassic HD[®] Hip System is in compliance with LAL testing requirements for orthopedic implants.