July 6, 2018

MicroPort Orthopedics Inc.
Allen Mamaril
Regulatory Affairs Specialist I
5677 Airline Road
Arlington, Tennessee 38002

Re: K173776
Trade/Device Name: BIOLOX delta Option and Extra-long Heads
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
Dated: June 1, 2018
Received: June 4, 2018

Dear Allen Mamaril:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173776

Device Name
BIOLOX® Delta Option and Extra-long Heads

Indications for Use *(Describe)*
MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

MicroPort Orthopedics Inc.

510(K) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the BIOLOX® *delta* Option and Extra-long Heads.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington, TN, 38002 Phone 866-872-0211 Fax: 855-466-2247
Date:	December 11, 2017
Contact Person:	Allen Mamaril *Regulatory Affairs Specialist I*
Proprietary Name:	BIOLOX® *delta* Option and Extra-long Heads
Common Name:	Femoral Head, Neck Sleeve
Classification Name and Reference:	21 CFR 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis—Class II
Subject Product Code and Panel Code:	Orthopedics/87/LZO
Predicate Device:	Femoral Head: K130376 DYNASTY® Acetabular System with Ceramic Neck Sleeve: K072656 DYNASTY® Acetabular System
Reference Device:	Femoral Head: K140043 DYNASTY® Acetabular System with Ceramic K953025 SLT 28mm XXL Femoral Head K141653 Biolox® *delta* Option Ceramic Heads K131684 Biolox® *delta* Ceramic heads K131518 Mectacer Biolox Option Heads K112115 Mectacer Biolox Delta Heads Neck Sleeve: K141653 Biolox® *delta* Option Ceramic Heads K131518 Mectacer Biolox Option Heads

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DEVICE INFORMATION

A. Intended Use

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

B. Device Description

The BIOLOX® *delta* Option and Extra-long Heads include femoral heads and neck sleeves. The design features are summarized below:

- Femoral Heads
  - BIOLOX® *delta* Option:
    - Manufactured from alumina matrix composite
    - Head sizes: 28mm, 32mm, 36mm, 40mm, 44mm
    - Conical Bore: 16/18 Taper
  - BIOLOX® *delta* Extra-long:
    - Manufactured from alumina matrix composite
    - Head Sizes: 32mm, 36mm, 40mm
    - Conical Bore: 12/14 Taper
- Neck Sleeves
  - BIOLOX® *delta* Option:
    - Manufactured from titanium alloy
    - Neck Sleeve sizes: Short, Medium, Long, and Extra-long
    - Conical Bore: 16/18 External Taper, 12/14 Internal Taper

C. Substantial Equivalence Information

The design features and materials of the BIOLOX® *delta* Option and Extra-long Heads are substantially equivalent to those of the predicate devices cleared under K130376 and K072656. The indications of the subject devices are identical to the predicates. The fundamental scientific technology of the subject devices has not changed relative to the predicate devices. The safety and effectiveness of subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

D. Nonclinical Testing

The subject BIOLOX® *delta* Option femoral heads were evaluated mechanically for static (or pre-fatigue) burst strength and post-fatigue burst strength.

The subject devices were evaluated for the stability of the taper system subjected to traction forces between the BIOLOX® *delta* Option femoral head and BIOLOX® *delta* Option neck sleeve by conducting an axial pull off test to measure distraction forces.

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Rotational stability tests were also performed to measure the torque required to twist the BIOLOX® *delta* Option femoral head on the tapers.

Lastly, the subject devices were tested for fretting corrosion of the BIOLOX® *delta* Option sleeve and tapers of the stem/neck mating components.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Biocompatibility

Biocompatibility information for the subject devices is included in the cited Master File. The intended patient contact, materials, colorants, manufacturing steps and processing additives used in the subject implant devices are identical to those of the predicate and reference devices. Therefore, additional biocompatibility testing was not completed on the subject devices.

The subject devices are implanted using existing specialized trial and impactor instruments, for which colorant and biocompatibility information were reviewed by FDA in K170444.

G. Component and Accessory Compatibility

Tables 1 and 2 show the compatibility of the subject devices with previously cleared MicroPort Orthopedics products.

Table 1. Compatible Shells and Liners, Including 510(k) information

510(k)	Device Name
K061547	DYNASTY® Beaded Shells and Liners
K070785	DYNASTY® Beaded Shells and Liners
K082924	DYNASTY® BIOFOAM® Shells and Liners
K122382	DYNASTY® BIOFOAM® Shells and Liners
K142119	PROCOTYL® L Beaded Shells and Liners
K170444	PROCOTYL® PRIME Shell and Liners
K171181	PROCOTYL® PRIME E-CLASS™ Shells and Liners

Table 2. Compatible Femoral Components, Including 510(k) Information

510(k)	Device Name
K003016	PRO-FEMUR R
K012091	PRO-FEMUR
K021346	STEM HIP REPLACEMENT SYSTEM
K041114	PROFEMUR TAPERED HIP STEM
K041586	PROFEMUR S HIP STEM
K051995	PROFEMUR RENAISSANCE HIP STEM
K052915	PROFEMUR XTR HIP STEM
K053588	PROFEMUR LX HIP STEM
K060358	PROFEMUR TL HIP STEM

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K080663	PROFEMUR LX REVISION 5/8 COATED HIP STEM
K081090	PROFEMUR LX 5/8 COATED HIP STEM
K091423 K100866	PROFEMUR HIP SYSTEM MODULAR NECKS
K110399	GLADIATOR PLASMA CLASSIC HIP STEM
K111698	PROFEMUR(R) E CEMENTLESS HIP STEM
K111699	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM
K111910	GLADIATOR HIP STEM
K112080	PRESERVE HIP STEM
K112150	PROFEMUR GLADIATOR HA HIP STEM
K121221	PROFEMUR Z REVISION HIP STEM
K123434	PROFEMUR Z CLASSIC STEM
K123688	PROFEMUR TL CLASSIC STEM
K130984	PROFEMUR RENAISSANCE CLASSIC STEM
K140676	PROFEMUR TL CLASSIC LONG NECK HIP STEMS
K141235	PROFEMUR RENAISSANCE CLASSIC LONG NECK HIP STEMS
K150133	PROFEMUR PRESERVE SIZE 1-3 HIP STEMS
K150302	PROFEMUR PRESERVE CLASSIC STEM

H. Conclusions

The safety and effectiveness of the BIOLOX® *delta* Option and Extra-long Heads are adequately supported by the substantial equivalence information, materials information, and nonclinical testing data provided within this premarket notification.