b-One Ortho Corp.
Allison Gecik
Regulatory Affairs Associate Director
3 Wing Drive Suite #259
Cedar Knolls, New Jersey 07927

Re: K202768
Trade/Device Name: KOSMO Femoral 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
Dated: February 25, 2021
Received: February 26, 2021

Dear Allison Gecik:

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 Vuniqi
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202768

Device Name
b-ONE™ Total Hip System

Indications for Use *(Describe)*

The b-ONE™ Total Hip System is intended for primary or revision total hip replacement in skeletally mature patients with a severely disabled hip joint and/or hip damage due to the following conditions:

Osteoarthritis, traumatic arthritis, avascular necrosis of the femoral head, noninflammatory degenerative joint disease (NIDJD), slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.
Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis and congenital dysplasia; treatments of nonunion, acute traumatic fracture of the femoral head or neck; failed endoprosthesis, femoral osteotomy, or Girdlestone resection; and fracture-dislocation of the hip.

The b-ONE™ Total Hip System KOSMO™ HA coated stems are intended for cementless use only.
The b-ONE™ Total Hip System KOSMO™ stainless steel stems are intended for cemented use only.

b-ONE™ Total Hip System components are not intended for use with other total hip systems.

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.

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TRADITIONAL
510(K) SUMMARY
As required by 21 CFR 807.92

Submitter Information:

Submitter's Name:	b-ONE ORTHO, Corp.
Address:	3 Wing Drive
	Suite 259
	Cedar Knolls, NJ 07927
Telephone:	866-276-4538
Contact Person:	Allison Gecik
Telephone:	973-587-8431

Date Prepared: September 18, 2020

Proprietary Name: b-ONE™ Total Hip System

Classification: Class II

Classification Panel: Orthopedic

Common Name: Total Hip Joint Replacement

Product Code(s): LZO, MEH

Classification Name(s):

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis	(888.3353)

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed: K070554, K042992 DePuy Corail Stem; DePuy Corail AMT Stem

Legally Marketed Reference Devices Used to Support Substantial Equivalence: K192189, K182048 Zimmer Biomet Avenir Complete Hip Stem

Intended Use: The b-ONE™ Total Hip System is intended for primary or revision total hip replacement in skeletally mature patients with a severely disabled hip joint and/or hip damage due to the following conditions:

Osteoarthritis, traumatic arthritis, avascular necrosis of the femoral head, noninflammatory degenerative joint disease (NIDJD), slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis and congenital dysplasia; treatments of nonunion, acute traumatic fracture of the femoral head or neck; failed endoprosthesis, femoral osteotomy, or Girdlestone resection; and fracture-dislocation of the hip.

The b-ONE™ Total Hip System KOSMO™ HA coated stems are intended for cementless use only. The b-ONE™ Total Hip System KOSMO™ stainless steel stems are intended for cemented use only.

b-ONE™ Total Hip System components are not intended for use with other total hip systems.

Device Description/Technological Characteristics:

The b-ONE Total Hip System is an artificial hip replacement system comprised of femoral stems and mating femoral heads; acetabular shells and mating acetabular liners; optional acetabular bone screws. The therapeutic effect is replacement of the diseased joint with artificial components to restore joint function. Compatibility of the femoral head to the stem is only claimed for the b-ONE Total Hip System. There is no allowed interchangeability with systems manufactured by other companies.

This 510(k) premarket notification is being submitted as a line extension to the current b-ONE Total Hip System by adding a bone compacting Femoral Stem component. The KOSMO™ Femoral Stem is compatible with the b-ONE™ Primary Acetabular components. The KOSMO™ Cementless Femoral Stem components are compatible with the b-ONE™ 12/14 Taper CoCr or Ceramic Femoral Heads. The KOSMO™ Cemented Femoral Stem components are compatible with the b-ONE™ 12/14 Taper Ceramic Femoral Heads only.

b-ONE Total Hip System KOSMO Femoral Stem consists of cementless and cemented bone compacting stem options. The KOSMO Femoral Stem is composed of HA coated titanium alloy Ti-6Al-4V-ELI (ASTM F136) for cementless stems and Stainless Steel (ASTM F1586) for cemented stem. All system components are supplied sterile and are single use devices.

Comparison of Technological Characteristics (compared to Predicate(s))

The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The b-ONE Total Hip System KOSMO™ Femoral Stem and the predicate devices share the following characteristics:

- Materials of construction
- Manufacturing processes
- Sizes offered
- Product design for shape
- Coatings
- Sterilization methods

Performance Testing - Bench

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Studies

• Endurance and Performance	• Range of Motion Study
• Impingement Testing	• Bacterial Endotoxin Testing
• Biocompatibility	• Shelf Life Studies

Conclusion

The information provided above supports that the b-ONE™ Total Hip System KOSMO™ Femoral Stem is as safe and effective as the predicate devices with the same intended use. Some minor differences in design and technology exist between the subject and predicate devices, however applicable reference devices have been cited to support the conclusion that these differences do not raise any new questions of safety and effectiveness. The b-ONE™ Total Hip System KOSMO™ Femoral Stem is substantially equivalent to the predicate devices.