November 15, 2024

b-ONE Ortho, Corp.
Allison Gecik
Director, US Quality & Regulatory
3 Wing Drive
Suite 259
Cedar Knolls, New Jersey 07927

Re: K240528
Trade/Device Name: b-ONE® Total Hip System
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, JDI
Dated: October 18, 2024
Received: October 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240528

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 and Grit-Blasted stems are intended for cementless use only.
The b-ONE® Total Hip System KOSMO™ Stainless Steel stems are intended for cemented use only.
The b-ONE® Cement Restrictor is intended to restrict bone cement migration into the distal medullary canal and aid in cement pressurization during total hip arthroplasty.
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.

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

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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: November 15, 2024

Proprietary Name: b-ONE® Total Hip System

Classification Panel: Orthopedic

Classification: Class II

Classification Regulation/Product Codes:

Subject Devices	Product Code	Regulation Number	Regulation Name
b-ONE® Total Hip System	LZO	888.3353	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
	MEH	888.3353	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
	JDI	888.3350	Hip joint metal/polymer semi-constrained cemented prosthesis

Predicate Device and Reference Devices:

Predicate and Reference Device Alignment to the b-ONE® Total Hip System Components			
Subject Devices	Primary Predicate Device Per Component	Corresponding Predicate Regulatory Information (Primary)	Applicable Reference Devices
b-ONE® Total Hip System	(K202768), The b-ONE™ Total Hip System KOSMO™ Femoral Stems	888.3353 LZO, MEH	(K070554; K042992), DePuy Corail Stem; DePuy Corail AMT Stem

			(K182705) b-ONE Total Hip System Juveno Femoral Stem (K030122), DePuy Summit Basic Press-Fit Hip Prosthesis (K800894), Depuy Cement Restrictor Trials & Instruments

Indications for 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 and Grit-Blasted stems are intended for cementless use only.

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

The b-ONE® Cement Restrictor is intended to restrict bone cement migration into the distal medullary canal and aid in cement pressurization during total hip arthroplasty.

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

Device Description/Technological Characteristics for b-ONE Total Hip System KOSMO Femoral Stem

b-ONE Total Hip System KOSMO Femoral Stem consists of cementless and cemented bone compacting stem options. The b-ONE KOSMO Femoral Stems Sizes are offered in 12 femoral stem sizes ranging from size 0 to 10 with half size of 4.5 for Cementless Collarless/Collared Standard, High, and Proportional Offset families and 11 femoral stem sizes ranging from size 1 to 10 with half size of 4.5 for Cementless Collarless/Collared Coxa Vara families and Cemented Standard and Proportional Offset families.

The subject stems are laser marked with the catalog number, lot number, company logo, size, and material. The KOSMO Femoral Stem is composed of titanium alloy Ti-6Al-4V-ELI (ASTM F136) for cementless stems and Stainless Steel (ASTM F1586) for cemented stems. The cementless stems are offered as either HA coated or Grit-blasted.

Device Description/Technological Characteristics for b-ONE Total Hip System Cement Restrictor

The b-ONE Cement Restrictor is made from UHMWPE (ASTM F648/ISO 5834-1). The restrictor is offered in 7 different sizes with a major diameter of 9, 11, 13, 15, 17, 20, and 23mm and have a total length of 17mm. The cement restrictor is to be used for cement implantation. This b-One Cement Restrictor is intended to restrict bone cement migration into the distal medullary canal and aid in cement pressurization during total hip arthroplasty.

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® Hip System components and the primary predicate device share the following characteristics:

- Materials of construction
- Sizes within the same range
- Similarity in shape
- Coatings
- Fixation
- Sterilization methods

Differences between the subject components and primary predicate device include: introduction of grit-blasted stems, additional neck geometries and offsets and cement restrictor is being introduced for use with the subject cemented stems.

Performance Testing - Bench

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

Non-Clinical Studies for b-ONE Total Hip System KOSMO Femoral Stem & Cement Restrictor

• Range of Motion (ISO 21535)	• Endotoxin Testing (USP<85>)
• Cemented Stem Distal Fatigue (ISO 7206-4)	• Cementless Stem Distal Fatigue (ISO 7206-4)
• Cemented Stem Neck Fatigue (ISO 7206-6)	• Cementless Stem Neck Fatigue (ISO 7206-6)
• Material Characterization	• Biocompatibility Assessment (ISO 10993-1)

Conclusion

This subject 510(k) premarket notification is being submitted as a line extension to the existing b-ONE® Total Hip System devices. Additional stem options and a cement restrictor are being submitted to add to the previously cleared b-ONE Kosmo Femoral Stem System (K202768).

The information provided above supports that the b-ONE® Total Hip System components are as safe and effective as the predicate devices with similar intended uses. 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 components are substantially equivalent to the predicate devices.