



April 13, 2026

B-One Ortho, Corp.
Allison Gecik
Director, US Quality & Regulatory
3 Wing Dr., Suite 259
Cedar Knolls, New Jersey 07927

Re: K253357

Trade/Device Name: b-ONE® Bipolar Head

Regulation Number: 21 CFR 888.3390

Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis

Regulatory Class: Class II

Product Code: KWY

Dated: December 1, 2025

Received: December 1, 2025

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

510(k) Number (if known)
K253357

Device Name
b-ONE® Bipolar Head

Indications for Use (Describe)

The Bipolar Head is intended to be used for hemi-hip arthroplasty with evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem and is indicated in the following conditions:

1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
3. Avascular necrosis of the femoral head
4. Non-union of femoral neck fractures.
5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

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: 973-965-8940
 Contact Person: Allison Gecik

Date Prepared: April 12, 2026

Proprietary Name: b-ONE® Bipolar Head

Classification Panel: Orthopedic

Classification: Class II

Classification Regulation/Product Codes:

Subject Devices	Product Code	Regulation Number	Regulation Name
b-ONE® Bipolar Head	KWY	888.3390	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

Predicate Device and Reference Device:

Predicate and Reference Device		
Predicate Device	Corresponding Predicate Regulation(s)	Corresponding Predicate Product Code(s)
K812672, DePuy Self Centering Hip (Primary)	888.3390	KWY
K800207, Stryker UHR Bipolar (Reference)	888.3360	KWL
K855231; K972792, Stryker Centrax (Reference)	888.3390	KWY

Indications for Use:

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5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

Device Description/Technological Characteristics

The Bipolar Head is a hemi-hip component consisting of a CoCr (ASTM F75) shell, UHMWPE (ASTM F648) Liner and UHMWPE (ASTM F648) Retaining ring.

The single assembled bipolar head implant construct provides primary articulation at the femoral head and inner polyethylene bearing interface, and secondary articulation at the outer shell and acetabulum interface. The internal aspect of the shell is designed to lock the polyethylene liner utilizing a polyethylene ring. The outer metal surface of the bipolar implant allows for articulation with the patient's acetabulum. The Bipolar Head is compatible with the b-One CoCr and ceramic heads size 28mm (K173380). This device is offered in 26 sizes ranging from 40-65mm each with a 28mm head.

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 Bipolar Head and the predicate devices share the following characteristics:

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

Performance Testing - Bench

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

Non-Clinical Studies for Bipolar Head

• Material Characterization	• Endotoxin Testing (USP<85>)
• Range of Motion Testing (ISO 21535)	• Biocompatibility Assessment (ISO 10993-1)
• Impingement Testing (ASTM F2582)	• Pull-off and lever-off disassembly of Bipolar Head
• Wear Testing Assessment	

Conclusion

This subject 510(k) premarket notification is being submitted as a line extension to the existing b-ONE[®] Hip System devices. The b-ONE Bipolar Head is being introduced to be compatible with the Kosmo Femoral Stems(cleared under K202768; K240528) as well as Juveno Femoral Stems (cleared under K182705).

Where minor differences in design and technology exist between the subject and predicate devices, performance testing/evaluations and additional comparisons to reference devices were used to support substantial equivalence.