September 8, 2026

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

Re: K262341
Trade/Device Name: b-ONE® Mobio™ Total Knee System Revision Cemented Tibial Augments, Stem Extensions and Press-Fit Stem Extensions
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: July 9, 2026
Received: July 10, 2026

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2026.09.08 16:30:05 -04'00'

for Lixin Liu, 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262341

Please provide the device trade name(s).

b-ONE® Mobio™ Total Knee System Revision Cemented Tibial Augments, Stem Extensions and Press-Fit Stem Extensions

Please provide your Indications for Use below.

The MOBIO Total Knee System is intended for total knee arthroplasty due to the following conditions:
• Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post -traumatic arthritis
• Post-traumatic loss of knee joint configuration and function
• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
• Revision of previous unsuccessful knee replacement or other procedure
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques
Additional Indications for the Posterior Stabilized (PS) and Posterior Stabilized Plus (PS+) components:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint
• Absent or nonfunctioning posterior cruciate ligament
• Severe anteroposterior instability of the knee joint
The MOBIO Total Knee System is intended for implantation with bone cement only. The MOBIO Press-Fit Stem Extensions are intended for cementless applications.
MOBIO Total Knee System components are not intended for use with other knee systems.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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:	973-965-8940

Date Prepared: September 4, 2026

Common Name: Total Knee Replacement System

Proprietary Name: b-ONE® Mobio™ Total Knee System Revision Cemented Tibial Augments, Stem Extensions and Press-Fit Stem Extensions

Classification Panel: Orthopedic

Classification: Class II

Classification Regulation/Product Codes:

Subject Devices	Product Code	Regulation Number	Regulation Name
b-ONE® Mobio™ Total Knee System Revision Cemented Tibial Augments, Stem Extensions and Press-Fit Stem Extensions	JWH	888.3560	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis

Predicate Device and Reference Device:

Predicate and Reference Device Alignment to the b-ONE® Mobioö Total Knee System Components			
Subject Devices	Primary Predicate Device Per Component	Corresponding Predicate Regulatory Information (Primary)	Applicable Reference Devices
b-ONE® Mobio™ Total Knee System Revision Cemented Tibial Augments, Stem Extensions and Press-Fit Stem Extensions	(K222431), Mobio™ Total Knee System Stemmed Baseplate and Stem Extensions	888.3560 JWH	(K053514), Stryker Triathlon Knee (K160700) DePuy Attune Cemented Stems (K181947) Zimmer Persona Revision Cemented Stems (K043440) Smith & Nephew LEGION Stem Extensions

Indications for Use:

The MOBIO Total Knee System is intended for total knee arthroplasty due to the following conditions:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post -traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture- management techniques

Additional Indications for the Posterior Stabilized (PS) and Posterior Stabilized Plus (PS+) components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or nonfunctioning posterior cruciate ligament
- Severe anteroposterior instability of the knee joint

The MOBIO Total Knee System is intended for implantation with bone cement only. The MOBIO Press-Fit Stem Extensions are intended for cementless applications.

MOBIO Total Knee System components are not intended for use with other knee systems.

Device Description/Technological Characteristics for Mobio™ Revision Cemented Tibial Augments

The Revision Cemented Tibial Augments are manufactured from titanium alloy (Ti-6Al-4V) conforming with ASTM F1472. The Revision Cemented Tibial Augments are compatible with the Mobio™ Stemmed Baseplate (and Stem Extensions). The augments are symmetrical (i.e. can be used in either left or right orientations) and are available in five sizes/footprints in either 5 or 10mm thickness.

Device Description/Technological Characteristics for Mobio™ Tibial Stem Extensions

The Tibial Stem Extensions subject to this 510(k) premarket notification are manufactured from titanium alloy (Ti6Al4V ELI) conforming to ASTM F136. The purpose of this 510(k) premarket notification submission is to expand the current size offering for the Tibial Stem Extensions to include 5 additional diameters (10, 18, 20, 22, and 24mm) with various lengths ranging from 30-180mm.
The stems are intended for cemented fixation, and the bone contacting surface is grit blasted using a #24 sized Aluminum Oxide grit blast.

Device Description/Technological Characteristics for Mobio™ Press-Fit Stem Extensions

The Press-Fit Stem Extensions are optional components that may be used to provide additional fixation of the knee prosthesis construct and are compatible with the Mobio™ Stemmed Baseplates. The Mobio™ Stemmed Baseplates mate with the modular Stem Extensions through a threaded junction. The Press-Fit Stem Extensions size offering will include 8 diameters (10, 12, 14, 16, 18, 20, 22, and 24mm) with various lengths ranging from 60-180mm. The Press-Fit Stem Extensions are manufactured from Ti6Al4V ELI conforming to ASTM F136 and are intended for cementless fixation (press-fit applications).

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® Mobio™ Total Knee System components and the predicate devices share the following characteristics:

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

Minor differences have been noted between the subject and predicate devices in terms of sizing and surface finish. However, the minor differences do not present any different questions regarding safety or effectiveness.

Performance Testing - Bench

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

• Stemmed Baseplate Fatigue Testing Assessment	• Endotoxin Testing (USP<85>)
• Stemmed Baseplate Stem Torque Testing Assessment	• Biocompatibility Assessment (ISO 10993-1)

Conclusion

This subject 510(k) premarket notification is being submitted as a line extension to the existing Mobio™ Total Knee System. The Mobio™ Total Knee System is a modular artificial knee replacement system comprised of symmetric cemented femoral components, symmetric cemented tibial tray, symmetric tibial inserts with locking wires, symmetric patellar resurfacing button, and reusable surgical instruments. The Mobio™ Revision Cemented Tibial Augments are compatible with the Mobio™ Stemmed Tibial Baseplates (cleared under K222431). The therapeutic effect is replacement of the diseased joint with artificial components to restore joint function.

In addition, we are submitting this 510(k) premarket notification to expand the size offering of the Stem Extensions to be used with the Mobio™ Stemmed Tibial Baseplates (cleared under K222431) as well as introduce new Press-Fit Stem Extensions that are also indicated to be used with the Mobio™ Stemmed Tibial Baseplates.

The information provided above supports that the b-ONE® Mobio™ Total Knee 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 different questions of safety and effectiveness. The b-ONE® Mobio™ Total Knee System components are substantially equivalent to the predicate devices.