October 12, 2018

b-One Ortho Corp.
% Allison Gecik
Regulatory Affairs Manager
3 Wing Drive
Suite #259
Cedar Knolls, New Jersey 07929

Re: K180446
Trade/Device Name: b-ONE Total Knee System
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: September 5, 2018
Received: September 6, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Peter G. Allen -S
2018.10.12 12:11:22 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180446

Device Name
b-ONE Total Knee System

Indications for Use *(Describe)*

The b-ONE 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 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 b-ONE Total Knee System is intended for implantation with bone cement only.
b-ONE Total Knee System components are not intended for use with other knee 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 5, 2018

Proprietary Name: b-ONE Total Knee System

Classification: Class II

Classification Panel: Orthopedic

Common Name: Total Knee Joint Replacement

Product Code(s): JWH

Classification Name(s):	Regulation Number
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal Polymer knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis	888.3560

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed: Stryker Triathlon Total Knee Replacement System, K031729, K070095

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

Stryker Scorpio NRG, K030978
Zimmer NexGen LPS, K960279
Zimmer NexGen Fluted Stemmed Tibial Component, K963148
Depuy Attune PS, K111433
Omni Life Science Apex Knee System, K060192
Zimmer Persona, K121771
Zimmer NexGen All Poly Patella, K933785

Intended Use:

The b-ONE 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 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 b-ONE Total Knee System is intended for implantation with bone cement only.

b-ONE Total Knee System components are not intended for use with other knee systems.

Device Description/Technological Characteristics:

The b-ONE Total Knee System is a modular artificial knee replacement system comprised of symmetric cemented femoral components with optional femoral distal pegs, symmetric cemented tibial baseplate, symmetric tibial inserts with locking wires, symmetric patellar resurfacing button, and reusable surgical instruments. The therapeutic effect is replacement of the diseased joint with artificial components to restore joint function. The system is a posterior stabilized device type and includes two options for posterior stabilization, a PS and a PS+. The PS+ is designed with additional constraint when more stability is required. Compatibility of the system components is only claimed with the b-ONE Total Knee System. There is no allowed interchangeability with systems manufactured by other companies.

The System includes left and right femoral components manufactured from cast cobalt chrome. The system includes 30 sizes. Sizes 1-10 are provided in right and left versions. Sizes 3-7 are provided in both standard and narrow configurations, with the narrow sizes having a relatively smaller aspect ratio of the medial-lateral to anterior-posterior widths when compared to the standard sizes. Optional modular distal pegs are included in the system.

The system includes a Patella Component offered in seven sizes of variable diameter and thicknesses. The bone fixation surface incorporates three fixation pegs. The Patella Components are made from Conventional UHMWPE.

The system includes Tibial Inserts which are offered in 40 sizes, size A/1-4 through HJ/7-10 with 8 thicknesses and 48 sizes for PS+ inserts, size A1-2+ through HJ/7-10+ with 8 thicknesses. The Tibial Inserts are made from Conventional UHMWPE. The Tibial Inserts are pre-assembled with a locking wire which is manufactured from Cobalt Chrome alloy.

The system includes Tibial Baseplates offered in 9 sizes ranging from A-J. Tibial Baseplates are manufactured from forged titanium alloy.

All system components are supplied sterile and are single use devices.

Comparison of Technological Characteristics

The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The b-ONE® Total Knee System and the predicate devices share the following characteristics:

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

Performance Data

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

Non-Clinical Studies

- Tibial Baseplate Fatigue
- Locking Mechanism Strength
- Tibial Post Fatigue
- Constraint
- Contact Area and Contact Stress
- Tibiofemoral Range of Motion
- Characterization of UHMWPE Insert Material
- Bacterial Endotoxin Testing
- Shelf Life Studies
- Biocompatibility

Conclusion

The information provided above supports that the b-ONE Total Knee System 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 Knee System is substantially equivalent to the predicate devices.