November 4, 2021

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

Re: K212912
Trade/Device Name: OneFix Biocomposite Anchors, OneFix Biocomposite Small Anchors, OneFix All Suture Anchors, OneFix Interference Screws, OneFix Cannula System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, MBI, HWC, HRX
Dated: September 10, 2021
Received: September 13, 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

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K212912

Device Name

OneFix Biocomposite Anchors, OneFix Biocomposite Small Anchors, OneFix All Suture Anchors, OneFix Interference Screws, OneFix Cannula System

Indications for Use *(Describe)*

The OneFix Biocomposite Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee and elbow in the following procedures:
Shoulder: Rotor Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, lliotibial Band Tenodesis;
Elbow: Biceps Tendon Reattachment, UInar or Radial Collateral Ligament Reconstruction.

The OneFix Biocomposite Small Anchors are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Hip: Capsular repair, Acetabular Labral repair

(Continued)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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510(k) Number *(if known)*

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Device Name

OneFix Biocomposite Anchors, OneFix Biocomposite Small Anchors, OneFix All Suture Anchors, OneFix Interference Screws, OneFix Cannula System

Indications for Use *(Describe)*

(p.2/2)

The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The OneFix All Suture Anchor may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, they may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.

The OneFix Biocomposite Interference Screws are indicated for fixation of bone-tendon-bone or soft tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) reconstruction.

The OneFix Cannula System is intended for introduction of instrumentation through a portal for surgical procedure.

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.

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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:	973-965-8940

Date Prepared: September 10, 2021

Proprietary Name: OneFix Biocomposite Anchors, OneFix Biocomposite Small Anchors, OneFix All Suture Anchors, OneFix Interference Screws, OneFix Cannula System

Classification: Class II

Classification Panel: Orthopedic

Common Name:
Biodegradable Orthopedic Bone Screw
Screw, Fixation, Bone
Non-absorbable Suture Anchor
Arthroscope

Product Code(s): MAI; HWC; MBI; HRX

Classification Name(s):	Regulation Number
Single/multiple component metallic bone fixation appliances and accessories	888.3030
Smooth or threaded metallic bone fixation fastener	888.3040
Arthroscope	888.1100

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed:
Fixone Biocomposite Anchors; K192484
Fixone Biocomposite Small Anchors; K192032
Fixone All Suture Anchors; K192709
Fixone Interfernece Screws; K193497
JOINIX Cannula System; K162070

Intended Use:

OneFix Biocomposite Anchors: The OneFix Biocomposite Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee and elbow in the following procedures:
Shoulder: Rotor Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, lliotibial Band Tenodesis;
Elbow: Biceps Tendon Reattachment, UInar or Radial Collateral Ligament Reconstruction.

OneFix Biocomposite Small Anchors: The OneFix Biocomposite Small Anchors are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Hip: Capsular repair, Acetabular Labral repair

OneFix All Suture Anchors: The non-absorbable suture anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The OneFix All Suture Anchor may be used in either arthroscopic or open surgical procedures. After the suture strands are anchored to the bone, they may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. In conjunction with appropriate postoperative immobilization throughout the healing period, the suture anchor systems stabilize the damaged soft tissue.

OneFix Biocomposite Interference Screws: The OneFix Biocomposite Interference Screws are indicated for fixation of bone-tendon-bone or soft tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) reconstruction.

OneFix Cannula System: The OneFix Cannula System is intended for introduction of instrumentation through a portal for surgical procedure.

Device Description/Technological Characteristics:

The OneFix Biocomposite Anchors consist of cannulated anchors with an eyelet. They are pre-loaded on an insertion device. The anchor is manufactured from PLGA copolymer and β-TCP. A non-absorbable suture manufactured from cobraided UHMWPE/PET is inserted into the anchor and then implanted using the provided driver. There are 96 model codes over 4 families. The anchors widths range from 3.0mm through 6.5mm and lengths of 11.9mm through 16.8mm.

The OneFix Biocomposite Small Anchors consist of cannulated anchors with an eyelet. They are pre-loaded on an insertion device. The anchor is manufactured from PLGA copolymer and β-TCP. A non-absorbable suture manufactured from cobraided UHMWPE/PET is inserted into the anchor and then implanted using the provided driver. There are 9 model codes corresponding to variations of sutures with anchor dimensions (11.9mm x 2.4mm x 3.0mm).

The OneFix All Suture Anchors consist of one "fixed suture" and 2 or 3 non-absorbable sutures. The non-absorbable suture is manufactured from UHMWPE and PET fibers. The OneFix All Suture Anchor is implanted using its self-punching option and are pre-loaded on a handled insertion device. They come in 14 various model codes.

The OneFix Biocomposite Interference Screws are inserted into the bone tissue and the external thread is screw shaped and the inside of the screw is start shaped. The screws are manufactured from PLGA copolymer and β-TCP. There are 36 model codes with outside diameter ranging from 7-12mm and 20-35mm lengths.

The OneFix Cannula Systems is intended to puncture through tissue to make a pathway for surgical instruments during surgery. It consists of a cannula and a trocar made of polycarbonate. There are 3 types of this product: threaded, smooth and all smooth and comes in 72 model codes with inside diameter of 4.3mm through 8.1mm and lengths of 84mm through 130mm.

All implant components are provided sterile and are designated as single use. The system also includes the reusable surgical instruments required for implantation.

Comparison of Technological Characteristics

The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The OneFix Biocomposite/All Suture Anchors and Interference Screws and Cannula Systems and the predicate devices share the following characteristics:

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

Conclusion

The information provided above supports that the OneFix Biocomposite/All Suture Anchors and Interference Screws and Cannula Systems are as safe and effective as the predicate devices with the same intended use. The OneFix Biocomposite/All Suture Anchors and Interference Screws and Cannula Systems are substantially equivalent to the predicate devices.