September 11, 2023

Jarmon Medical, LLC (DBA Legends Orthopedics)
% W. Victoria Rogers
Regulatory Affairs Consultant
Rogers Consulting
11110 Arranmore Cove
Roanoke, Indiana 46783

Re: K230517
Trade/Device Name: Legends Orthopedics Suture Anchors (Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends Orthopedics 5.5 mm Knotless Suture Anchor)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 24, 2023
Received: July 24, 2023

Dear W. Victoria Rogers:

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,

Sara S. Thompson -S

For

Jesse Muir, 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K230517

Device Name
Legends Orthopedics Suture Anchors
(Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends Orthopedics 5.5 mm Knotless Suture Anchor)

Indications for Use *(Describe)*

The Legends Orthopedics 5.5 mm Suture Anchors is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle, and knee.
Specific indications are as follows:
Shoulder: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
Wrist/Hand: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.
Foot/Ankle: Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
Elbow: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.
Knee: a Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure.

The Legends Orthopedics 2.9 mm Suture Anchor is indicated for use in soft tissue reattachment procedures.
Specific indications are as follows:
Shoulder: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
Wrist/Hand: Scapholunate ligament reconstruction.
Elbow: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.
Knee: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.

The Legends Orthopedics 5.5 mm Knotless Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee.
Specific indications are as follows:
Shoulder indications: - Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
Wrist/Hand indications: - Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.
Foot/Ankle indications: - Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.
Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure.

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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**510(k) Summary**
**[As required by 807.92(a)]**

## 1. 510(k) Summary

### 1.1. Submitter Information:

Legends Orthopedics
169 E. Reynolds Road, Suite 203B
Lexington, Kentucky 40517

Contact Person: Jeremy Jarmon
Title: President/CEO
Telephone: 800-741-3995

Designated Submission Correspondent:
W. Victoria Rogers
Rogers Consulting
11110 Arranmore Cove
Roanoke, Indiana 46783
574-265-8356

Date prepared: 11 September 2023

### 1.2. Device Identification:

Trade Name: Legends Orthopedics Suture Anchors (Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends Orthopedics 5.5 mm Knotless Suture Anchor)

Common Name: Suture Anchor

Classification Name: Fastener, fixation non-degradable, soft tissue

Device Classification: Class II

Regulation Number: 21 CFR 888.3040

Product Code : MBI

### 1.3. Predicate Device:

Table 1: Predicate details

| Device Name | 510(k) Number |
|---|---|
| RoG™ Sports Medicine Suture Anchor | K111590 |

### 1.4. Device Description

The Legends Orthopedics Suture Anchors (Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends Orthopedics 5.5 mm Knotless Suture Anchor) are an internal fixation device intended to aid in arthroscopic and orthopedic reconstructive procedures needing soft tissue fixation, due to injury or degenerative disease.

The subject device(s) is screw-like in shape and composed exclusively of PEEK plastic. The 5.5mm (17.5mm length) is available in both standard "knotted" and "knotless" configurations. The implantable anchor devices are available in diameters of 5.5mm (17.5mm length) and 2.9mm diameter (10mm length) and provided in sterile condition.

They 5.5mm & 2.9 Suture Anchors are provided sterile and supplied with non-absorbable polyethylene suture. The anchor is supplied with reusable taps and guides of corresponding size.

The 5.5 knotless Suture Anchors are provided sterile no suture.
Components are available in a range of sizes to meet the needs of an individual patient.

The 5.5mm suture anchor is supplied in two designs:

with USP #2 high strength non-absorbable polyethylene suture(s) intended to be knotted and Knotless without any suture and suture attachment does not require knot tying.

The 2.9mm suture anchor is supplied in two designs:

i. with USP #2 high strength non-absorbable polyethylene suture(s) and where the anchor must be attached to the inserter before use and

ii. where the anchors are provided preloaded on single use inserters.

The anchors are composed of polyetheretherketone (PEEK). The high strength suture is made from non-absorbable Ultra High Molecular Weight Polyethylene (UHMWPE). The implants are ethylene oxide (ETO) sterilized. All implants are supplied in sterile condition.

### 1.5 Intended Use & Indications for Use

The **Legends Orthopedics 5.5 mm Suture Anchors** is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle, and knee.

Specific indications are as follows:

Shoulder: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.

Wrist/Hand: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.

Foot/Ankle: Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.

Elbow: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.

Knee: a Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure.

The **Legends Orthopedics 2.9 mm Suture Anchor** is indicated for use in soft tissue reattachment procedures.

Specific indications are as follows:

Shoulder: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.

Wrist/Hand: Scapholunate ligament reconstruction.

Elbow: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.

Knee: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.

The **Legends Orthopedics 5.5 mm Knotless Suture Anchor** is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee.

Specific indications are as follows:

Shoulder indications: - Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.

Wrist/Hand indications: - Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.

Foot/Ankle indications: - Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.

Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.

Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure.

**1.6 Summary of Technological Characteristics:**

The fundamental scientific technology, materials of construction and mechanism of operation is identical between the subject device **Legends Orthopedics Suture Anchors** (Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends Orthopedics 5.5 mm Knotless Suture Anchor) and the predicate device.

The rationale for substantial equivalence is based on consideration of the following characteristics:

- Intended Use: Identical to predicate
- Indications for Use: Identical to predicate
- Materials: Identical to predicate
- Design Features: Identical to predicate
- Sterilization: Identical to predicate

Table 2 summarizes the comparison of technological characteristics between the subject and predicate device

Table 2: Substantial Equivalence Table

| S. No. | **Parameters** | **Legends Orthopedics Suture Anchors** (Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends | **RoG Sports Medicine Suture Anchor, K111590 (**predicate device**)** | **Comments** |
|---|---|---|---|---|

| | | Orthopedics 5.5 mm Knotless Suture Anchor) (subject device) | | |
|---|---|---|---|---|
| 1. | Manufacturer | Legends Orthopedics | RoG™ Sports Medicine | - |
| 2. | Product Code | MBI | MBI | Same |
| 3. | Regulation Number | 21 CFR 888.3040 | 21 CFR 888.3040 | Same |
| 4. | Classification | Class II | Class II | Same |
| 5. | Intended Use/ Indications for Use | The *Legends Orthopedics 5.5 mm* Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:<br><br>Shoulder: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.<br><br>Wrist/Hand: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.<br><br>Foot/Ankle: Achilles tendon repair/reconstruction, hallux valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.<br><br>Elbow: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.<br><br>Knee: a Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial | The RoG Sports Medicine 5.5 mm Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:<br><br>Shoulder: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.<br><br>Wrist/Hand: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.<br><br>Foot/Ankle: Achilles tendon repair/reconstruction, hallux valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.<br><br>Elbow: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.<br><br>Knee: a Lateral collateral ligament repair, medial collateral ligament repair, | Same |

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|---|---|---|---|---|
| | | band tenodesis, joint capsule closure.<br><br>The Legends Orthopedics 2.9 mm Suture Anchor is indicated for use in soft tissue reattachment procedures. Specific indications are as follows:<br><br>Shoulder: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.<br><br>Wrist/Hand: Scapholunate ligament reconstruction.<br><br>Elbow: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.<br><br>Knee: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.<br>The Legends Orthopedics 5.5 mm Knotless Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:<br><br>Shoulder indications: - Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or | posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure.<br><br>The RoG Sports Medicine 2.9 mm Suture Anchor is indicated for use in soft tissue reattachment procedures. Specific indications are as follows:<br><br>Shoulder: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.<br><br>Wrist/Hand: Scapholunate ligament reconstruction.<br><br>Elbow: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.<br><br>Knee: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.<br>The RoG Sports Medicine 5.5 mm Knotless Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, | Same |

| | | | | |
|---|---|---|---|---|
| | | capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.<br><br>Wrist/Hand indications: - Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.<br><br>Foot/Ankle indications: - Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.<br><br>Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.<br><br>Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure. | elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:<br><br>Shoulder indications: - Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.<br><br>Wrist/Hand indications: - Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.<br><br>Foot/Ankle indications: - Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.<br><br>Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.<br><br>Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. iliotibial band tenodesis, joint capsule closure. | |
| | Design | | | |
| 6. | Anchor Diameters | 2.9mm Anchor<br>5.5mm Anchor | 2.9mm Anchor<br>5.5mm Anchor | Same |
| 7. | Anchor Geometry | 2.9mm Anchor: 10mm length<br>5.5mm Anchor: 17.5mm length | 2.9mm Anchor: 10mm length<br>5.5mm Anchor: 17.5mm length | Same |

| | | | | |
|---|---|---|---|---|
| 8. | Anchor Material | polyetheretherketone (PEEK) | polyetheretherketone (PEEK) | Same |
| 9. | Suture Material | USP #2 Ultra High Molecular Weight Polyethylene (UHMWPE) | USP #2 Ultra High Molecular Weight Polyethylene (UHMWPE) | Same |
| 10. | Suture Configuration | Braided multifilament (supplied by Riverpoint Medical, K100006) | Braided multifilament (supplied by Riverpoint Medical, K100006) | Same |
| 11. | Range of Suture Diameter | .50-.599 (USP #2) | .50-.599 (USP #2) | Same |
| 12. | Method of Fixation of Suture to Anchor | Knotted Design:<br>Distal eyelet of anchor<br><br>Knotless Design:<br>through body of anchor | Knotted Design:<br>Distal eyelet of anchor<br><br>Knotless Design:<br>through body of anchor | Same |
| 13. | Sterilization | Provided in Sterile conditions (EO Sterilization). | Provided in Sterile conditions (EO Sterilization). | Same |
| 14. | Single Use/Reuse | Single Use | Single Use | Same |
| 15. | Shelf Life | 5 years | 5 years | Same |

### 1.7 Summary of Performance Data

**Non-Clinical Tests:**

Non-clinical laboratory testing was performed by RoG Sports Medicine to determine substantial equivalence. The results were reviewed and side by side comparisons were done with the identified predicate device and it demonstrated that there were no significant differences between the **Legends Orthopedics Suture Anchors** (Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends Orthopedics 5.5 mm Knotless Suture Anchor) and the predicate device.

The results indicated that the devices were functional within their intended use.

| **Predicate device K111590** | Proposed device |
|---|---|
| ASTM F2026-17 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications | Same |
| SP-NF M80200_04_01<br>Non-absorbable Surgical Suture | Same |
| USP-NF M99670_02_01<br><881> Tensile Strength | Same |

| | |
|---|---|
| USP-NF M99650_02_01<br><861> Sutures - Diameter | Same |
| ISO 11135-1:2007 Sterilization of Healthcare Products – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices. | Same |
| ISO 10993-7:2008 “Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals” | Same |
| ISO 11607-1:2006 – “Packaging for terminally sterilized medical devices--Part 1: Requirements for materials, sterile barrier systems and packaging systems. | Same |
| ISO14971:2007 “Medical Devices – application of risk management to medical devices” | Same |
| ASTM F543 (Standard Specification and Test Methods for Metallic Bone Screws) as a guideline Guidance Document for Testing Bone Anchor Devices | Same |
| The mechanical and physical properties were compared to the minimum requirements specified in ASTM F 2026 for surgically implantable grade of PEEK | Same |

**1.8 Clinical Tests:**

None provided as a basis for substantial equivalence.

**1.9 Substantial Equivalence Conclusion:**

The Legends Orthopedic Suture Anchors (Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends Orthopedics 5.5 mm Knotless Suture Anchor) under this premarket notification submission are the same in design, intended use, technological characteristics, sterilization and are composed of the same materials as its predicate. This product has the same performance characteristics and conforms to the same standards. There are no differences between the subject device and the predicate devices regarding safety and effectiveness that would affect the use of the product. As such, the Legends Orthopedic Suture Anchors are the same as its primary predicate.

From the data available we can justify that the Legends Orthopedic Suture Anchors (Legends Orthopedics 5.5 mm Suture Anchors, Legends Orthopedics 2.9 mm Suture Anchor, and Legends Orthopedics 5.5 mm Knotless Suture Anchor) are safe, and as effective and performs the same indications for use as that of already marketed predicate device identified in 1.3 of 510(k) summary.

There are no significant differences between the subject device and the predicate devices that would adversely affect the use of the product.