December 16, 2022

Auxein Medical Private Limited
Rahul Luthra
Director
Plot No. 168, 169, 170 Phase-IV, Sector 57, Kundli
Industrial area
Sonipat, Haryana 131028
India

Re: K213110
Trade/Device Name: AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor, AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 30, 2022
Received: October 3, 2022

Dear Rahul Luthra:

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,

Laura C. Rose -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213110

Device Name
AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor
AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor

Indications for Use *(Describe)*

1. AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor

The AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

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.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction;

Hip: Capsular Repair, Acetabular Labral Repair.

2. AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor

The AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.

Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

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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Section 6.0: 510(k) Summary

Pre Market Notification 510(k) Summary as required by section 807.92
General Company Information as required by 807.92 (a)
A.1: The Submitter's Name, address, telephone number, a contact person, and the date the summary was prepared.

Submitter's Name:	Auxein Medical Private Limited
Address:	**Auxein Medical Private Limited** Plot No. 168-169-170, Phase-4, Kundli Industrial Area, HSIIDC, Sector-57, Sonepat-131028, Haryana, India
Contact Person Name:	Mr. Rahul Luthra
Title:	Director
Email Id:	info@auxein.com
Phone Number:	+91 9560557733
Dated:	16.12.2022

Person Responsible for Regulatory Compliance

Name:	Mr. Mohit Kumar
Title:	Management Representative
Mail Id:	m.kumar@auxein.com
Dated:	16.12.2022

Throughout the submission of AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor and AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor is covered under 510(k) Submission.

A.2: The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Proprietary Name:

- AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor
- AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor

Common or Usual Name:
Suture Anchor

Classification Name:
Fastener, fixation, Nondegradable, soft tissue

Product Code:
MBI

Device Class: II

Review Panel: Orthopedic

Regulation Number:
21 CFR 888.3040

Primary Product Code	Classification Name	Common Name	Regulation Number
MBI	Fastener, fixation, Nondegradable, soft tissue	Bone Anchor, Soft Tissue Fixation Device	21 CFR 888.3040

A.3) Identification of the Predicate Device:
Following are the predicate device 510(k) with which we are declaring substantial equivalence:
The following is the range of variants covered with their corresponding predicate devices.

Primary Predicate:

510k Number	**K170327**
Applicant	Parcus Medical LLC.
Common Name	Suture Anchor
Device Name	Parcus SLiK Anchor

Secondary Predicate:

510k Number	**K120449**
Applicant	Depuy Mitek
Common Name	Bone Anchor
Device Name	HEALIX ADVANCE™ PEEK Anchor

A.4) A description of the device that is the subject of the pre market notification submission, such as might be found in the labelling or promotional material for the device

Device Description:
The AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor and AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor are non-absorbable threaded suture anchor manufactured in PEEK Material. Generally, it is indicated for the attachment of soft tissue to the bone.
The anchor comes preloaded on a disposable inserter assembly and is intended for fixation of size 2 suture to bone. The suture options may include needles to facilitate suture passage through tissue.
The detailed description for both of the devices (AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor and AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor) are as follows:

AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor
AUXILOCK® PEEK OPTIMA Screw-In Suture anchor is a fully threaded suture anchor featuring

dual threads to maximize cortical and cancellous fixation. AUXILOCK® PEEK OPTIMA Screw-In Suture anchor has a flat tip to protect the sutures and to facilitate the insertion. The anchor is particularly suitable for repairing rotator cuff and associated pathologies. AUXILOCK® PEEK OPTIMA Screw-In Suture anchor is available in diameter of 4.5, 5.5 and 6.5mm. This anchor is available with two or three BioBraid suture. The anchors are also available with needles which are ideal for mini-open rotator cuff repair procedures. The following categories of products are included in AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor:

- AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor with Two #2 BioBraid: White & White/Blue, with Needles: MO-6
- AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor with Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor with Three #2 BioBraid: White/Blue, White/Black & White
- AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor with Two #2 BioBraid: White & White/Blue, with Needles: MO-6
- AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor with Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor with Three #2 BioBraid: White/Blue, White/Black & White
- AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor with Two #2 BioBraid: White & White/Blue, with Needles: MO-6
- AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor with Two #2 BioBraid: White/Blue & White/Black

AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor

AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchors are fully threaded knotless anchors. These anchors are designed to be used with sutures or tapes for rotator cuff repair employing the ‘bridge’ technique. Moreover, the ‘knotless’ technique consists of passing sutures or tapes of the medial row anchors through the tissue. They are finally inserted into the bone socket once they’re loaded through the Rotador anchor eyelet. This technique eliminates possible complications caused by knots compared to other conventional anchors. The anchor is available in 4.75, 5.5 and 6.25mm diameter with PEEK OPTIMA anchor body and eyelet. The following categories of products are included in AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor:

- AUXILOCK® Rotador 4.75mm x 15mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Rotador 5.5mm x 15mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Rotador 6.25mm x 15mm PEEK OPTIMA Screw-In Anchor

These implants are sold in sterile conditions (Ethylene Oxide Sterilization).
The system is indicated for use in adult patients only. All implants are for single use only.
The AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor and AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor consists of Peek OPTIMA (Grade LT1) as per ASTM F2026-17 implantable Class II, Anchors, UHMWPE (Ultra-High Molecular Weight Polyethylene) Suture as per ASTM F2848-17.

Note: The #2 Biobraid Suture is not to be used as a stand-alone. It should be used only with the assembled implant.

A.5) Indications for Use:

AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor
The AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

Shoulders: 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.
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction;
Hip: Capsular Repair, Acetabular Labral Repair.

AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor
The AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.
Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment.
Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

A.6) Summary of Technological Characteristics as compared to the predicate devices:
A comparison between the Auxein's devices (AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor & AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor) and predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

Following is the summary of parameters in which the comparison has been verified:

S.No.	Characteristics	Subject Device	Predicate Device K120449 (HEALIX ADVANCE™ PEEK Anchor) K170327 (Parcus SLiK Anchor)

1.	Product Code	MBI	MBI
2.	Regulation Number	21 CFR 888.3040	21 CFR 888.3040
3.	Regulatory Class	II	II
4.	Indications for Use	**AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor** The AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications: **Shoulders**: 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. **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis. **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction; **Hip**: Capsular Repair, Acetabular Labral Repair.	**K120449 (HEALIX ADVANCE™ PEEK Anchor)** **Shoulders**: 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. **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis. **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction; **Hip**: Capsular Repair, Acetabular Labral Repair. **K170327 (Parcus SLiK Anchor)** The Parcus SLiK Anchor are indicated for attachment of soft tissue to bone. This product is

		AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor The AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications: **Shoulder**: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. **Elbow**: Tennis Elbow Repair, Biceps Tendon Reattachment. **Hand/Wrist**: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Triangular fibrocartilage complex (TFCC).	intended for the following indications: **Shoulder**: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. **Elbow**: Tennis Elbow Repair, Biceps Tendon Reattachment. **Hand/Wrist**: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.
5.	Sterilization	Provided in Sterile conditions (EO Sterilization).	Provided in Sterile conditions (EO Sterilization).

6.	Dimensional Verification	The same dimensions are found in both new devices as well as Predicate devices.	
7.	Shelf-life	5 Years	5 Years
8.	Single Use/Reuse	Single Use	Single Use
9.	Operating Principle	It can be used for single incision, soft tissue, or bone-tendon-bone fixation.	It can be used for single incision, soft tissue, or bone-tendon-bone fixation.

Technological Comparison (between AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor and Parcus SLiK Anchor):

S.No.	Characteristics	Subject Device (AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor)	Predicate device, K170327 (Parcus SLiK Anchor)
1.	Product Code	MBI	MBI
2.	Regulation Number	21 CFR 888.3040	21 CFR 888.3040
3.	Common Name	Suture Anchor	Suture Anchor
4.	Classification Name	Fastener, fixation, Nondegradable, soft tissue	Fastener, fixation, Non degradable, soft tissue
5.	Regulatory Class	II	II
6.	Indications for Use	The AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications: **Shoulder**: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band	The Parcus SLiK Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications: **Shoulder**: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band

		Tenodesis, Patellar Ligament and Tendon Avulsion Repair. **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. **Elbow**: Tennis Elbow Repair, Biceps Tendon Reattachment. **Hand/Wrist**: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Triangular fibrocartilage complex (TFCC).	Tenodesis, Patellar Ligament and Tendon Avulsion Repair. **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. **Elbow**: Tennis Elbow Repair, Biceps Tendon Reattachment. **Hand/Wrist**: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.
7.	Sterilization	Provided in Sterile conditions (EO Sterilization).	Provided in Sterile conditions (EO Sterilization).
8.	Dimensional Verification	The same dimensions are found in both new devices as well as Predicate devices.	
9.	Shelf-life	5 Years	5 Years
10.	Single Use/Reuse	Single Use	Single Use
11.	Operating Principle	It can be used for single incision, soft tissue, or bone-tendon-bone fixation.	It can be used for single incision, soft tissue, or bone-tendon-bone fixation.

Technological Comparison (between HEALIX ADVANCE™ PEEK Anchor and AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor):

S.No.	Characteristics	**Subject Device** (**AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor**)	**Predicate Device**, K120449 **(HEALIX ADVANCE™ PEEK Anchor**)
1.	Product Code	MBI	HWC
2.	Regulation Number	21 CFR 888.3040	21 CFR 888.3040
3.	Common Name	Suture Anchor	Bone Anchor
4.	Classification Name	Fastener, fixation, Nondegradable, soft tissue	Smooth or threaded metallic bone fixation fasteners
5.	Regulatory Class	II	II
6.	Indications for Use	The AUXILOCK® PEEK	

		OPTIMA Screw-In Suture Anchor are indicated for attachment of soft tissue to bone. This product is intended for the following indications: **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. **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis. **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction; **Hip**: Capsular Repair, Acetabular Labral Repair.	**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. **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis. **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction; **Hip**: Capsular Repair, Acetabular Labral Repair.
7.	Sterilization	Provided in Sterile conditions (EO Sterilization).	Provided in Sterile conditions (EO Sterilization).
8.	Dimensional Verification	The same dimensions are found in both new devices as well as Predicate devices.	
9.	Shelf-life	5 Years	5 Years
10.	Single Use/Reuse	Single Use	Single Use
11.	Operating Principle	It can be used for single incision, soft tissue, or bone-tendon-bone fixation.	It can be used for single incision, soft tissue, or bone-tendon-bone fixation.

12.	Suture Size	#2	#2

Justification for difference in Product Code:

The Secondary Predicate, K120449 (HEALIX ADVANCE™ PEEK Anchor) have Product Code HWC (screw, fixation, bone) which falls under regulation 21 CFR 888.3040.

Our Subject device (AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor) have Product Code MBI (fastener, fixation, non degradable, soft tissue) which falls under regulation 21 CFR 888.3040.

The AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor is intended to be used for soft tissue fixation. So, we have included MBI as product Code.

Although there is a difference in product codes of our device and secondary predicate device but design, material, indications are identical between of our device and secondary predicate device.

So, Considering all these points we can conclude that the product code difference is not a significant difference which can affect safety and performance of the subject device.

B.1) Discussion on the non-clinical testing performed

Following are the applicable product standards considered for non-clinical standards:

- Material Standards
- Biocompatibility Standards
- Performance Bench Standards.
- Sterilization, shelf-life and packaging for sterile product.
- Bacterial Endotoxin

Non-Clinical Test Summary:

Bench tests were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject device complies with the following standards:

Material Standards:

The material standards are the essential part to be complied with first, as it is the basis of manufacturing surgical implants.

We have complied with the following material standards:

- **ASTM F2026-17**: Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.
- **ASTM F2848-17**: Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns.
- **ASTM F899-12**: Standard Specification for Wrought Stainless Steels for surgical instruments.

Note: We have used Grade 304 of Stainless steel Material for instruments as per ASTM F899-20, UHMWPE for Suture as per ASTM F2848-17 and PEEK OPTIMA (Grade LT 1, from Invibio) as per ASTM F2026-17 for Implants.

Summary of Biocompatibility

The device in its final finished form has been evaluated for biocompatibility according to ISO 10993-3.

Conclusion of Mechanical performance bench test:

The following are the mechanical tests that have been performed on the Subject device (i.e. AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor and AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor) and Predicate device (i.e. Depuy Mitek, HEALIX ADVANCE™ PEEK Anchor and K170327, Parcus SLiK Anchor respectively):

1. Insertion Test
2. Pull-Out Tensile Static.
3. Pull-out following Cyclic Loading Test.

Sterilization, shelf-life and packaging for sterile product

Sterilization: ETO Sterilization

The ETO sterilization has been performed to sterilize this medical device. EO penetrates the packaging, making contact with all accessible surfaces of the product to deliver the required sterility assurance level (SAL).

Trace levels of EO and ethylene chlorohydrin (ECH) may remain on products after an EO sterilization process. To detect these traces, EO residual test was done. ISO 10993-7 outlines the specific limits of EO and ECH that must not be exceeded in order to ensure product and patient safety.

- ISO 11135: 2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 17665-1:2006, Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO/TS 17665-2:2009, Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1.
- ISO/TS 17665-3:2013 (en), Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization.
- ISO 11140-1:2014, Sterilization of health care products — Chemical indicators — Part 1: General requirements.
- ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods- Part 1: Estimation of population of microorganisms on products.
- ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods- Part 2: Tests of sterility performed in the validation of a sterilization process.

Packaging of the Product: Tyvek Packaging

The integrity of the final package is maintained at least for the claimed shelf-life of the medical device.

The tyvek pouch is used for the packaging of AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor and AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor. The double sterile barrier is used for the packaging.

We have followed the below standards for packaging of the device:

- ISO 11607-1:2006/AMD 1:2014 Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging system.
- ISO 11607-2:2006/AMD 1:2014 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.

Shelf-life: 5 years

The stability study has been done to determine the shelf life.

We have followed the below standards for performing shelf-life of the device:

- ASTM F1980:2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ASTM F88/F88M:2015 Standard test method for seal strength of flexible barrier materials.
- ASTM F1929:2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

Bacterial Endotoxin

- USP <85> Bacterial Endotoxin Test.
- USP <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests.

Bacterial Endotoxin Test (BET): We perform Bacterial Endotoxin Test of every sterile batch products by using acceptance criteria as endotoxin testing limit must be <20EU/Device (as the products are general medical devices for implantation). The testing is done by using Limulus amebocyte lysate (LAL) test. The testing procedure is performed as per the standards USP 85 and ANSI/AAMI ST72:2019.

Conclusion:

There are no significant differences between the subject device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, and operational principles. From the data available we can justify that the AUXILOCK® PEEK OPTIMA Screw-In Suture Anchor and AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchor is as safe, and as effective and performs the same indications for use as that of already marketed predicate devices identified in A.3. of 510(k) summary.