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

Re: K213018
Trade/Device Name: Auxilock GFS Mini, GFS II Large, and GFS Ultimate
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 14, 2022
Received: October 19, 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,

Sara S. Thompson -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213018

Device Name
Auxilock GFS Mini, GFS II Large, and GFS Ultimate

Indications for Use *(Describe)*
Auxilock GFS Mini, GFS II Large, GFS Ultimate Mini and GFS Ultimate Large are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

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.

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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
Mail Id:	info@auxein.com
Phone Number:	+91 9560557733
Dated:	18.11.2022

Person Responsible for Regulatory Compliance

Name:	Mr. Mohit Kumar
Title:	Sr. Research Engineer
Mail Id:	m.kumar@auxein.com
Dated:	18.11.2022

Throughout the submission of Auxilock Graft Fixation System 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 Graft Fixation System

Common or Usual Name:
Fastener, Fixation, Non-Degradable, Soft Tissue

Classification Name:
Smooth or threaded metallic bone fixation fastener

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	Smooth or threaded metallic bone fixation fastener	Fastener, Fixation, Non-Degradable, Soft Tissue	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.

510K Number	**K202259**
Applicant	Parcus Medical, LLC
Common Name	Fastener, Fixation, Non-Degradable, Soft Tissue
Device Name	Parcus GFS

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 GFS Mini, GFS II Large & GFS Ultimate are a range of devices design for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair. Each device is made from a medical grade titanium alloy, Ti-6Al-4V ELI, grade 5 as per ASTM F136 and also includes an UHMWPE polyblend suture component as per ASTM F2848-17 .
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.

GFS Mini
GFS Mini is a continuous loop with an oblong shaped button indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair. Being a continuous loop without any joint, GFS mini eliminates the need for knot tying.
GFS Mini is available in various pre-measured loop sizes of 12, 15, 20, 25, 30, 35, 40, 45, 50 and 55mm. The pre-loaded pulling (#5 Biobraid, White) and Flipping (#5 Biobraid, White/Black) braided sutures are available to ensure controlled pulling and flipping of the button in the trans osseous tunnel. The continuous loop is made up of UHMWPE (Ultra-High Molecular Weight Polyethylene) and the oblong button (L 12mm X W 3.9mm X H 1.55mm) is made up of Titanium material.

GFS II Large
GFS II Large is a continuous loop with an oblong shaped button indicated for use in the fixation of

ligaments and tendons in patients requiring ligament or tendon repair. Being a continuous loop without any joint, GFS II Large eliminates the need for knot tying.
The GFS II Large includes a larger button (L 16.5mm X W 4.4mm X H 2.8mm) compared to GFS Mini which eliminates the need for a stepped tunnel technique. The pre-loaded pulling (#5 Biobraid, White) and Flipping (#5 Biobraid, White/Black) braided sutures are available to ensure controlled pulling and flipping of the button in the trans osseous tunnel. GFS II Large is available in various pre-measured loop sizes of 12, 15, 20, 25, 30, 35, 40, 45, 50 and 55mm. The continuous loop is made up of UHMWPE (Ultra-High Molecular Weight Polyethylene) while the oblong button is made up of Titanium material.

Fixed loop Suture Size
The suture used in GFS Mini and GFS II Large is fixed loop suture and have size of #5.

GFS Ultimate
GFS Ultimate is an adjustable loop with an oblong shaped button indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair. GFS Ultimate provides a double locking mechanism which eliminates the need for knot tying. GFS Ultimate provides three sutures (UHMWPE):

- *Adjustable Suture* (#7 Biobraid, White/Blue): The Adjustable Suture allows the surgeon to maximize the amount of graft inside the femoral tunnel. It also enables calibration of the loop to its optimum size.
- *Pulling Suture* (#5 Biobraid, White): The Pulling Suture is available to pull the graft inside the tunnel.
- *Flipping Suture* (#5 Biobraid, White/Black): The Flipping Suture ensures the flipping of the button on the lateral cortex of the tunnel.

GFS Ultimate fits into all tunnel lengths. The graft protection frame of the loop protects the graft from any damage or abrasion. The loop also eliminates the inventory needs, unlike continuous/closed/fixed loop.

AUXILOCK® BioBraid Sutures
AUXILOCK® BioBraid Sutures are braided sterile sutures prepared from Ultra High Molecular Weight Polyethylene (UHMWPE). BioBraid sutures are non-absorbable and do not impose any significant changes in tensile strength retention known to occur in vivo. BioBraid sutures are available in a variety of colour combinations for easy suture management in complicated repairs.

Note: The #5 Biobraid Suture and #7 Biobraid Suture are not to be used as a stand-alone. They should be used only with the assembled implant.

Suture color additives
The UHMWPE sutures when made up of tracers can be with blue polypropylene (pigment β-Cu-phthalocyanine blue) or polyamide black (pigment hematein).
The color additive FD&C Blue 2, color additive Black logwood and color additive phtalocyanine are according to FDA and it is approved for use in medical applications (§74.3102 – FDA), (§73.1410 –FDA) and (§74.3045 – FDA) respectively.

The Suture supplied meets all the United States Pharmacopeia (USP) requirements for non-absorbable suture.

Surgical instrumentation is included in the Auxilock Graft Fixation System to allow the placement and attachment of the button with the bone. Various reamer, drill bits, drill, Awl, pin, Tray, Graft station, Containers and other components are included with the Auxilock Graft Fixation System. These instruments are made from Stainless steel (SS 304) material as per ASTM F899.

A.5) A statement of the intended use of the device Indications for Use:

Auxilock GFS Mini, GFS II Large, and GFS Ultimate:
Auxilock GFS Mini, GFS II Large, GFS Ultimate are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

A.6) Summary of Technological Characteristics as compared to the predicate devices:
Substantial equivalence including comparison with predicate devices.
A comparison between the Auxein's Graft Fixation System 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.	Parameter of Conclusion	Scoped Device	Predicate Device	Remarks
1.	Product Code	MBI	MBI	Identical as predicate device.
2.	Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Identical as predicate device.
3.	Regulatory Class	II	II	Identical as predicate device.
4.	Intended Use	Auxilock GFS Mini, GFS II Large, GFS Ultimate are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair	The Parcus GFS are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.	Identical as predicate device.
5.	Sterilization	Provided in Sterile conditions (EO Sterilization).	Provided in Sterile conditions (EO Sterilization).	Equivalent as predicate device.
6.	Mechanical Test	Tensile Static and Pull out following cyclic loading test.	Tensile Static and Pull out following cyclic loading	Equivalent as predicate

	Performance		test.	device.
7.	Material Standards	Titanium Alloy and UHMWPE Suture.	Titanium Alloy and UHMWPE Suture.	Conform to the same material standard.
8.	Dimensional Verification	The same dimensions are found in both new devices as well as Predicate devices.		Equivalent as predicate device.
9.	Shelf-life	5 Years	5 Years	Identical as predicate device.
10.	Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
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.	Identical as predicate 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 test.
- 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 metallic surgical implants.

We have complied with the following material standards:

- **ASTM F136/ISO 5832-3**: Standard specification for wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.
- **ASTM F2848-17:** Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns.
- **ASTM F899-20:** Standard Specification for Wrought Stainless Steels for surgical instruments.

Note: We have used Grade 304 of Stainless steel (SS 304) Material for instruments as per ASTM F899-20 and Titanium Alloy (Ti-6Al-4V ELI) Grade 5 for Titanium Implants.

Summary of Biocompatibility

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

Summary of Performance test:

The following are the mechanical tests that have been performed on the Subject device (i.e. Auxilock Graft Fixation System) and Predicate device (i.e. Parcus Graft Fixation System):

1. Tensile Static and
2. Pull out following cyclic loading test..

The results of this testing indicate that the Auxilock Graft Fixation System is equivalent to a predicate device.

Sterilization, shelf-life and packaging for sterile product

We have complied with the below mentioned standards for sterilization, shelf-life and packaging for sterile products.

- 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.
- ISO 11607-1:2006/AMD1:2014 Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging system.
- ISO 11607-2:2006/AMD1:2014 Packaging for terminally sterilized medical devices - Part 2:Validation requirements for forming, sealing and assembly processes.
- ASTM F1980-21, 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 Test

Bacterial Endotoxin test was performed on Auxilock Graft Fixation System by using Limulus Amoebocyte Lysate (LAL) test. The Endotoxin testing limit was less or equal to 20EU/Device. The test was performed according to standard USP 32 chapter 85.

Shelf Life

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.

The shelf life study (accelerated Stability Study) was conducted on an Auxilock Graft Fixation System. As per the expiry assumption of 5 years, we have performed this study at 60°C and calculated that the accelerated stability study will be continued for 8 months. The bioburden test, sterilization, sterility test, visual inspection, dimensional check, Material integrity and package integrity test were performed on the subject device before starting the study and after the completion of the study. After completion of the study, the accelerated stability study was found to be satisfactory. Hence, we have concluded that the expiry of 5 years, which we have assumed complies. ASTM F1980:2016 was used as reference standard for performing this test.

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 as internal fixation components. From the data available we can justify that the Auxilock Graft Fixation System 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.