January 4, 2024

Healthium Medtech Limited
Pankaj Dawar
Deputy General Manager Regulatory Affair
472-D, 13th Cross, 4th Phase, Peenya Industrial Area
Bangalore, Karnataka 560058
India

Re: K231033
Trade/Device Name: CEPTRE® Knotted UHMWPE Suture PEEK Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 2, 2023
Received: December 4, 2023

Dear Pankaj Dawar:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.01.04 10:17:30 -05'00'

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)*
K231033

Device Name
CEPTRE® Knotted UHMWPE Suture PEEK Anchor

Indications for Use *(Describe)*
The CEPTRE® Knotted UHMWPE Suture PEEK Anchor are indicated in surgical procedures for soft tissue fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder and hip for the following indications:

1. Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair Capsular Shift or Capsulolabral Reconstruction.
2. Foot/Ankle: Lateral Stabilization, Medial stabilization, Achilles Tendon repair, Hallux Valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair/tendon repair, Digital tendon transfers and Bunionectomy.
3. Knee: Anterior Cruciate Ligament Repair, Medial Collateral ligament repair, Lateral collateral ligament repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair and Iliotibial band tenodesis.
4. Hand/Wrist: Scapholunate ligament reconstruction, Ulnar or Radial Collateral 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.
5. Elbow: Biceps tendon reattachment, Tennis Elbow Repair, Ulnar or Radial collateral ligament reconstruction, and lateral Epicondylitis repair.
6. Hip: Acetabular labral repair, Capsular repair and gluteus medius 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.

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1. 510(k) Summary

1.1. Submitter Information:

Application Correspondent: PANKAJ DAWAR

Healthium Medtech Limited

472-D, 13th Cross, 4th Phase,

Peenya Industrial Area,

Bangalore Karnataka 560058, India

Phone: +91-9886529934

E-mail: pankaj.d@healthiummedtech.com

Specification Developer: Healthium Medtech Limited

472-D, 13th Cross, 4th Phase,

Peenya Industrial Area,

Bangalore, Karnataka 560058, India

Phone: +91 - 80 - 41868000

Contact Person: PANKAJ DAWAR

E-mail: pankaj.d@healthiummedtech.com

Date Prepared: 03-01-2024

1.2. Device Identification:

Device Trade Name: CEPTRE® Knotted UHMWPE Suture PEEK Anchor.

Device Common Name: Non-Absorbable Suture Anchor

Classification Name: Smooth or threaded metallic bone fixation fastener.

Device Class: Class II

Regulation Number: 21 CFR 888.3040

Product Code: MBI

1.3. Predicate Devices:

Table 1 – List of Predicate Devices

Device Name	510(k) Number
Arthrex Corkscrew Suture Anchors	K143745
Arthrex SutureTak Suture Anchors	K140855

1.4. Device Description

The CEPTRE® Knotted UHMWPE Suture PEEK Anchors are available as Screw Anchor (threaded) & Wedge Anchor (Tap in) which are preloaded with suture(s), tape(s) or suture–tape combinations on a disposable inserter assembly. The implant is supplied sterile and ready to use.

1.5. Indications for Use

Indications for Use

The CEPTRE® Knotted UHMWPE Suture PEEK Anchor are indicated in surgical procedures for soft tissue fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder and hip for the following indications:

1. **Shoulder**: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair Capsular Shift or Capsulolabral Reconstruction.
2. **Foot/Ankle**: Lateral Stabilization, Medial stabilization, Achilles Tendon repair, Hallux Valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair/tendon repair, Digital tendon transfers and Bunionectomy
3. **Knee**: Anterior Cruciate Ligament Repair, Medial Collateral ligament repair, Lateral collateral ligament repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair and Iliotibial band tenodesis.
4. **Hand/Wrist**: Scapholunate ligament reconstruction, Ulnar or Radial Collateral 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.
5. **Elbow**: Biceps tendon reattachment, Tennis Elbow Repair, Ulnar or Radial collateral ligament reconstruction, and lateral Epicondylitis repair.
6. **Hip:** Acetabular labral repair, Capsular repair and gluteus medius repair.

1.6. Comparison of Technological Characteristics

The fundamental scientific technology, materials of construction and mechanism of operation are similar between the subject device CEPTRE® Knotted UHMWPE Suture PEEK Anchor and the predicate devices. **Table 2** summarizes the comparison of technological characteristics between the subject and predicate device.

Table 2 – Substantial Equivalence Table

S.No	Parameters	Arthrex Corkscrew Suture Anchors (K143745)	Arthrex SutureTak Suture Anchors (K140855)	CEPTRE® Knotted UHMWPE Suture PEEK Anchor (Subject Device)
1.	Manufacturer	Arthrex, Incorporated	Arthrex, Incorporated	Healthium Medtech Limited
2.	Product Code	MBI	MAI (Classification Product Code) MBI (Subsequent Product Code)	MBI
3.	Regulation Number	21 CFR 888.3040	21 CFR 888.3030	21 CFR 888.3040
4.	Classification	Class II	Class II	Class II
5.	Intended Use	The Arthrex Corkscrew suture anchors are intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, and elbow in the following procedures: • 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, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.	The Arthrex SutureTak suture 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-Clabicular 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	The CEPTRE® Knotted UHMWPE Suture PEEK Anchor are indicated in surgical procedures for soft tissue fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder and hip for the following indications: 1. **Shoulder**: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair Capsular Shift or Capsulolabral Reconstruction . 2. **Foot/Ankle**: Lateral Stabilization, Medial stabilization,

S.No	Parameters	Arthrex Corkscrew Suture Anchors (K143745)	Arthrex SutureTak Suture Anchors (K140855)	CEPTRE® Knotted UHMWPE Suture PEEK Anchor (Subject Device)
		• Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis. • Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction. • Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair. • Hip: Capsular repair, acetabular labral repair, gluteus medius repair.	• 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	Achilles Tendon repair, Hallux Valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair/tendon repair, Digital tendon transfers and Bunionectomy 3. **Knee**: Anterior Cruciate Ligament Repair, Medial Collateral ligament repair, Lateral collateral ligament repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair and Iliotibial band tenodesis. 4. **Hand/Wrist**: Scapholunate ligament reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments,

S.No	Parameters	Arthrex Corkscrew Suture Anchors (K143745)	Arthrex SutureTak Suture Anchors (K140855)	CEPTRE® Knotted UHMWPE Suture PEEK Anchor (Subject Device)
				Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital tendon transfers. 5. **Elbow**: Biceps tendon reattachment, Tennis Elbow Repair, Ulnar or Radial collateral ligament reconstruction, and lateral Epicondylitis repair. 6. **Hip**: Acetabular labral repair, Capsular repair and gluteus medius repair.
6.	Anchor Material	PEEK	PEEK	PEEK
7.	Suture / Tape Material	UHWMPE or a polyblend of UHMWPE and polyester	UHWMPE or a polyblend of UHMWPE and polyester	Suture-UHMWPE USP#2 Tape- UHMWPE 1.5mm Round-Flat-Round
8.	Design Feature	The Arthrex Corkscrew is fully threaded suture anchors designed for maximum fixation strength and simple insertion. An internal drive mechanism is combined with a unique eyelet to allow for continuous	The SutureTak Suture Anchors are threaded made up of PEEK material, designed for maximum fixation strength. The implant is provided preloaded on an inserter and may include eyelets which are preloaded with various types of suture, with or without needles.	The CEPTRE® Knotted UHMWPE Suture PEEK Anchors are available as Screw Anchor (threaded) & Wedge Anchor (Tap in) made up of PEEK, Preloaded with the suture(s), tape(s) or suture–tape combinations

S.No	Parameters	Arthrex Corkscrew Suture Anchors (K143745)	Arthrex SutureTak Suture Anchors (K140855)	CEPTRE® Knotted UHMWPE Suture PEEK Anchor (Subject Device)
		threads along the entire length of the anchor. The anchors are loaded with FiberWire sutures or tapes to provide superior repair strength.		made up of UHMWPE on the disposable Sterile Inserters.
9.	Specifications and Dimensions	• PEEK Corkscrew FT Suture Anchor, 4.5 mm x 14 mm w/two #2 FiberWire (1 Blue, 1 White/Black) • PEEK Corkscrew FT Suture Anchor, 4.75 mm x 14 mm w/two 1.3 mm SutureTapes (White/Black, White/Blue) • PEEK Corkscrew FT Suture Anchor, 4.75 mm x 14 mm w/two 1.3 mm SutureTapes (White/Black, White/Blue) • PEEK Corkscrew FT Suture Anchor, 5.5 mm x 14.7 mm w/three #2 FiberWire	• SutureTak Suture Anchor 2mm x 12mm #1 FiberWire • SutureTak Suture Anchor 2.4 mm x 12mm #2 FiberWire • SutureTak Suture Anchor 3 mm x 14mm #2 FiberWire • SutureTak Suture Anchor 3 mm x 14mm #2 FiberWire, qty. 2	**Wedge anchor:** • USP #2 Suture Loaded- 2.5mm, Length 12mm • USP #2 Double Sutures Loaded- 2.8mm, Length 12mm • 1.5mm Double Tapes Loaded- 2.8mm, Length 12mm **Screw anchor:** • USP #2 Suture & 1.5mm Tape Loaded- 4.8mm, Length 15mm • USP #2 Double Sutures Loaded- 4.8mm, Length 15mm • 1.5mm Double Tapes Loaded- 4.8mm, Length 15mm • USP #2 Suture &1.5mm Tape Loaded- 5.5mm, Length 15mm • USP #2 Double Sutures Loaded- 5.5mm, Length 15mm

S.No	Parameters	Arthrex Corkscrew Suture Anchors (K143745)	Arthrex SutureTak Suture Anchors (K140855)	CEPTRE® Knotted UHMWPE Suture PEEK Anchor (Subject Device)
		• PEEK Corkscrew FT Suture Anchor, 6.5 mm x 14.7 mm w/two #2 FiberWire		• 1.5mm Double Tapes Loaded- 5.5mm, Length 15mm • USP #2 Triple Sutures Loaded- 5.5mm, Length 15mm
10	Single Use/Reuse	Single Use	Single Use	Single Use
11	Shelf Life	5 Years	5 Years	5 Years
12	Sterilization Method	EtO	EtO	EtO
13	Performance Data	Insertion testing, Static pull-out Testing, Fatigue testing	Tensile testing Fatigue testing	Drive In Torque Pull-Out Test Cyclical Loading
14	Safety Data	No Data Available	No Data Available	• Skin Sensitization • Intracutaneous reactivity • Material Mediated Pyrogenicity • Acute Systemic Toxicity • In vitro cytotoxicity • Bone Implantation • Muscle Implantation • Bacterial Endotoxin

1.7. Summary of Performance Data

The CEPTRE® Knotted UHMWPE Suture PEEK Anchor and Predicate device underwent tests to determine their pull-out strength, cyclical loading and drive in torque test. Results demonstrated that the CEPTRE® Knotted UHMWPE Suture PEEK Anchor performs statistically equivalent to the predicate device.

1.8. Non-Clinical Testing

The Static pull out testing and cyclic loading were performed on the subject device to demonstrate that the differences do not negatively impact mechanical strength.

Bacterial endotoxin per USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.

Packaging testing was conducted to demonstrate shelf-life and confirm the packaging design provides a protective sterile barrier and protects the integrity of the products post sterilization during shipping and handling.

1.9. Conclusion

There are no significant differences between the subject device and the predicate devices that would adversely affect the use of the product. The subject device is substantially equivalent to the predicate devices (Arthrex Corkscrew Suture Anchors and Arthrex SutureTak Suture Anchors) in design, Intended use, Indications for use, function, Sterilization method, Shelf Life, and operational principles. From the data available we can justify that the CEPTRE® Knotted UHMWPE Suture PEEK Anchor is as safe, and as effective and performs the same indications for use as that of already marketed predicate device identified.