March 22, 2023

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

Re: K223889
Trade/Device Name: Stativ® Knotted UHMWPE 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: December 23, 2022
Received: December 27, 2022

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 (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

Laurence D. Coyne, Ph.D.
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)*
K223889

Device Name
STATIV® Knotted UHMWPE Suture Anchor

Indications for Use *(Describe)*

The STATIV® Knotted UHMWPE Suture Anchor is indicated for the fixation, by use of sutures, of soft tissue to bone in the following surgical procedures:

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, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction.
3. Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure.
4. Hand/Wrist: Scapholunate 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, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty).
5. Elbow: Biceps tendon reattachment, Ulnar or Radial collateral ligament reconstruction.
6. Hip: Acetabular labral repair, Capsular repair, Gluteal 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)

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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.
Contact Person:	PANKAJ DAWAR
Phone:	+ 91-80-41868000
E-mail:	pankaj.d@healthiummedtech.com
Date Prepared:	20-03-2023

1.2. Device Identification:

Device Trade Name:	STATIV® Knotted UHMWPE Suture 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: Predicate details

Device Name	510(k) Number
Arthrex FiberTak Suture Anchor (Primary)	K203268
Fixone All Suture Anchor (Secondary)	K192709

1.4. Device Description

The STATIV® Knotted UHMWPE Suture Anchor is a fixation device intended to provide secure fixation of soft tissue to bone and is available in self-tap/self-punching variant also. It consists of a soft Suture Anchor with attached non-absorbable suture(s) to an inserter with handle. The Anchor are available in various sizes, preloaded with suture, tape or suture–tape combinations. This device is provided sterile, for single use only.

Materials Specifications

1. Anchor :
   - Loop: Non-absorbable, UHMWPE USP #3, USP #7
   - Suture : Non-absorbable, UHMWPE USP #2
   - Tape : Non-absorbable UHMWPE 1.5mm Round-Flat-Round
   - Additive: Polycaprolactone (Average Mn 80,000)
2. Dispenser : Stainless Steel (SS 300 Series)
3. Handle : ABS (Acrylonitrile Butadiene Styrene)
4. Ring : Silicone Rubber Ring

1.5. Intended Use & Indications for Use

Intended Use

STATIV® Knotted UHMWPE Suture Anchor with the sutures/tapes are Intended for soft tissue fixation to the bone. These sutures/tapes may be incorporated, as components, into surgeries where constructs including those with allograft or auto graft tissues are used for repair.

Indications for Use

The STATIV® Knotted UHMWPE Suture Anchor is indicated for the fixation, by use of sutures, of soft tissue to bone in the following surgical procedures:

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, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction.

3. Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure.
4. Hand/Wrist: Scapholunate 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, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty).
5. Elbow: Biceps tendon reattachment, Ulnar or Radial collateral ligament reconstruction.
6. Hip: Acetabular labral repair, Capsular repair, Gluteal Tendon Repair.

1.6. Comparison of Technological Characteristics

The fundamental scientific technology, materials of construction and mechanism of operation are similar between the subject device STATIV® Knotted UHMWPE Suture Anchor and the predicate device.

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

Table 2: Substantial Equivalence Table

S. No	Parameters	Arthrex FiberTak Suture Anchor (K203268)	STATIV® Knotted UHMWPE Suture Anchor (Subject device)	Comments
1.	Manufacturer	Arthrex Inc.	Healthium Medtech Limited	-
2.	Product Code	MBI	MBI	Similar
3.	Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Similar
4.	Classification	Class II	Class II	Similar
5.	Intended Use	The Arthrex FiberTak Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures: **Elbow:** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction **Shoulder**: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair,	The STATIV® Knotted UHMWPE Suture Anchor is indicated for the fixation, by use of sutures, of soft tissue to bone in the following surgical procedures: 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	Similar

S. No	Parameters	Arthrex FiberTak Suture Anchor (K203268)	STATIV® Knotted UHMWPE Suture Anchor (Subject device)	Comments
		Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction **Hand/Wrist**: Scapholunate 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, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty) **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, Joint Capsule Closure **Hip**: Capsular repair, Acetabular labral repair, Gluteal Tendon Repair.	Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction. 3. Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure. 4. Hand/Wrist: Scapholunate 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, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty). 5. Elbow: Biceps tendon reattachment, Ulnar or Radial collateral ligament reconstruction. 6. Hip: Acetabular labral repair, Capsular repair, Gluteal Tendon Repair.	
6.	Anchor Loop Material	Hollow braid of polyester	UHMWPE	SE Analysis 1
7.	Suture & Tape Material	UHWMPE or a polyblend of UHMWPE and polyester	Suture- UHMWPE USP #2, Tape- UHMWPE 1.5mm flat	Similar
8.	Design	Arthrex Suture Anchor are designed to repair soft tissue to bone through a variety of innovative anchor styles, materials, and suture configurations. As the next	STATIV® Knotted UHMWPE Suture Anchor constructed of strong Ultra High Molecular Weight Polyethylene (UHMWPE) suture material. STATIV®	Similar

S. No	Parameters	Arthrex FiberTak Suture Anchor (K203268)	STATIV® Knotted UHMWPE Suture Anchor (Subject device)	Comments
		evolution of knotless rotator cuff repair, the FiberTak SpeedBridge technique is completed with FiberTak soft Anchor on the medial row and FiberTape® sutures fixated laterally with trusted SwiveLock® Anchor. This knotless repair creates a quick, secure construct in as few as three suture passing steps.	Knotted UHMWPE Suture Anchor is the Suture Anchor with sutures(s)/tape(s) combination. It assured centralized deployment of the anchor into pilot hole. Post deployment, the unique tri-pod bunched up pattern doubles its size, which gives much higher pull out strength.	
9.	Specifications and Dimensions	FiberTak Suture Anchor with #2 FiberWire CL (White/Blue) -- AR-3600 FiberTak Suture Anchor, double loaded with two #2 FiberWire CL (White/Blue, White/Black),- AR-3600-2 FiberTak with 1.3 mm SutureTape (White/Blue), - AR-3602 FiberTak Suture Anchor, Double Loaded with two 1.3 mm SutureTape (White/Blue, White/Black),- AR-3602-2 FiberTak with #2 TigerTail (Blue/Black) -AR-3603 FiberTak Suture Anchor, Double Loaded with two #2 TigerTail (Blue/Black and White/Black)- AR-3603-2 2.6 FiberTak Soft Anchor, Double Loaded with two #2 FiberWire CL (Blue/White, Black/White) -AR-3630-1 2.6 FiberTak Soft Anchor, Triple Loaded with three #2 FiberWire CL (Blue/White, Black/White, White)- AR-3631-1 2.6 FiberTak Soft Anchor, Double Loaded with two 1.3 mm	1.5mm Single Suture 1.8mm Single Suture 1.5mm Single Tape 1.8mm Single Tape 1.8mm Double Sutures 1.8mm Double Tapes 2.5 mm Double Sutures (Self-Tap) 2.5 mm Double Tapes (Self-Tap) 2.5 mm Triple Sutures (Self-Tap) 2.9 mm Double Sutures (Self-Tap) 2.9 mm Double Tapes (Self-Tap) 2.9 mm Triple Sutures (Self-Tap)	SE Analysis 2

S. No	Parameters	Arthrex FiberTak Suture Anchor (K203268)	STATIV® Knotted UHMWPE Suture Anchor (Subject device)	Comments
		SutureTape (White/Blue and White/Black) - AR-3632 2.6 FiberTak Soft Anchor, Triple Loaded with three 1.3 mm SutureTape (White/Blue, White/Black and White)- AR-3633		
10.	Single Use/Reuse	Single Use	Single Use	Similar
11.	Shelf Life	5 years	5 Years	Similar
12.	Sterilization	Provided in Sterile conditions (EO Sterilization).	Provided in Sterile conditions (EO Sterilization).	Similar
13.	Performance Data	Cyclic pull-out test, Bacterial Endotoxin	**Bench Performance:** Pull out Strength Cyclical Loading Bacterial Endotoxin	Similar
14.	Safety Data	No Data Available	**Biocompatibility:** Skin Sensitization, Intracutaneous reactivity, Material Mediated Pyrogenicity, Acute Systemic Toxicity, In vitro cytotoxicity.	-

SE Analysis 1:

Anchor Material:

Difference in Anchor Material does not affect the safety and efficacy of subject device based on the reference comparative study. Predicate device (K203268) has an anchor loop made up of Hollow braid of polyester, whereas the subject device has an anchor made up of UHMWPE.

From the literature study[1] it can be inferred that the Polyester suture had lower ultimate load than all groups of sutures used in the study except the suture composed of polyester and UHMWPE ($P<.05$). Pure UHMWPE suture had higher ultimate failure load than sutures composed of either polyester or polyester plus UHMWPE ($P<.05$). Predominant failure mode was suture cutting through the meniscus for the groups except for polyester suture which failed by suture rupture.

This literature study[1] shows that UHMWPE material has better ultimate load than the material used in predicate and this change is not raising any questions on the safety and efficacy of the subject device.

Reference 1: The influence of suture material on the strength of horizontal mattress suture configuration for meniscus repair.

[1] https://pubmed.ncbi.nlm.nih.gov/23340094/

SE Analysis 2:

Specification and Dimensions:

During the bench testing of subject device, it was observed that the changes in dimensions are not leading to any kind of new risks with the performance of subject device, and the acceptance criteria was met in each of the performance tests as per defined guidelines and applicable standards. By considering the performance data of the subject device, it is evident that the changes in dimensions are not causing and or does not affect the safety and efficacy of the product when comparing it with Predicate device. The different sizes of the subject device are determined through the diameter of the dispenser which is not implantable in nature, however, there is no change in the size of the implant, so the variation in sizes of the dispenser will not lead to any kind of new risks related to safety and performance.

1.7. Summary of Performance Data

The pull-out strength and displacement under cyclic loading of STATIV® Knotted UHMWPE Suture Anchor and Predicate device. 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 STATIV® Knotted UHMWPE Suture Anchor and the predicate device.

1.8. Clinical Testing

Not Applicable

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 device (Arthrex FiberTak Suture Anchor) in design, Intended use, Indications for use, function, Sterilization method, Shelf Life, and operational principles. From the data available we can justify that the STATIV® Knotted UHMWPE Suture Anchor is as 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.