August 4, 2023

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

Re: K231404
Trade/Device Name: T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button, T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 15, 2023
Received: May 15, 2023

Dear Dr. 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,

Jesse Muir -S

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)*
-

Device Name
T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button &
T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button

Indications for Use *(Describe)*
T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button are to be used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. This device is employed in Knee ligament repair and reconstructive procedures, specifically for ACL/PCL repair and reconstruction.

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:

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Contact Person:	PANKAJ DAWAR
E-mail:	pankaj.d@healthiummedtech.com
Date Prepared:	01-08-2023

1.2. Device Identification:

Device Trade Name:	T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button
Device Common Name:	Non-Absorbable Cortical Fixation
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	Predicate	510(k) Number
Arthrex ACL TightRope ®, PCL TightRope ®, and TightRope ® II	Primary Predicate	K221128*
ANCHORMAN Tibial Ligament Fixation Device	Reference Predicate	K170388

*** In K221128, Arthrex ACL TightRope® has been selected as the Primary Predicate.**

1.4. Device Description

The T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button is a permanently implantable Polyether Ether Ketone (PEEK) cortical tibial suspension fixation device which provides the orthopaedic surgeon a means of accurate fixation in ligament reconstructive surgeries and repair. The fixation device allows for endoscopic or open ligament reconstruction approaches.
The Closed button is preloaded with UHMWPE adjustable loop and in Open Button the UHMWPE adjustable loop is non preloaded.

1.5. Intended Use & Indications for Use

The T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button are to be used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. This device is employed in Knee ligament repair and reconstructive procedures, specifically for ACL/PCL repair and reconstruction.

1.6. Comparison of Technological Characteristics

The fundamental technology characteristics such as Design and Materials of construction are compared between the T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button with the primary predicate device Arthrex ACL Tightrope.

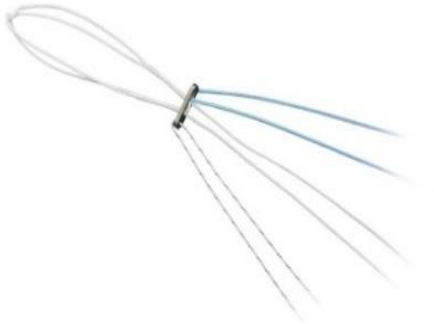
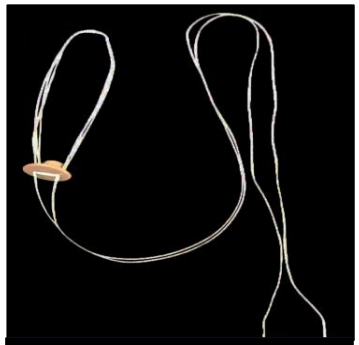
The Reference Predicate device **(K170388)** "ANCHORMAN Tibial Ligament Fixation Device" has the same material of construction as that of the subject devices i.e. PEEK

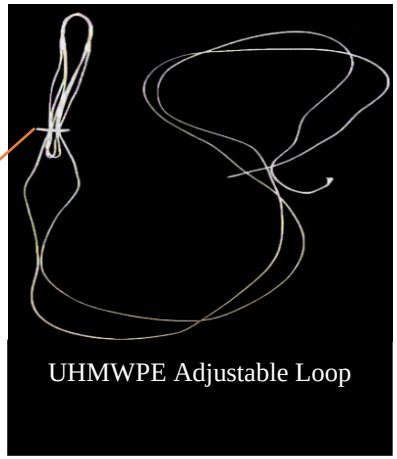
Table 2 summarizes the comparison of technological characteristics between the subject and predicate device.

Table 2 – Substantial Equivalence Table

S. No	Parameters	Arthrex ACL TightRope® (K221128) (Primary Predicate)	T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button (Subject Device)	Comments
1.	Manufacturer	Arthrex Inc.	Healthium Medtech Limited	-
2.	Product Code	MAI (Classification Product Code) MBI (Subsequent Product Code)	MBI	As the subject device is nondegradable so only MBI code is applicable.
3.	Regulation Number	21 CFR 888.3030 21 CFR 888.3040	21 CFR 888.3040	Similar to primary predicate device according to MBI code.
4.	Classification	Class II	Class II	Similar to predicate device
5.	Intended Use/Indications for Use	The Arthrex ACL TightRope ®, device is intended to be used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering these devices for ACL/PCL repair and	The Adjustable Loop UHMWPE Suture PEEK Button (Close Button & Open Button) are to be used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. This device is employed in Knee ligament repair and reconstructive procedures, specifically for ACL/PCL repair and reconstruction.	Similar to primary predicate device excluding the pediatric patient indications

S. No	Parameters	Arthrex ACL TightRope® (K221128) (Primary Predicate)	T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button (Subject Device)	Comments
		reconstruction for the adult and pediatric patient population.		
6.	Button Material	Titanium	PEEK	***SE Analysis 1***
7.	Loop Material	UHMWPE	**Closed Button Loop:** UHMWPE **Open Button Loop**: Non-absorbable, UHMWPE (UHMWPE 100.0%) + **Suture Button**: (Non-absorbable, UHMWPE (UHMWPE ≥ 88.0%) + Additive: Loctite 4014 (≤12.0% in the Suture Button))	***SE Analysis 2***

S. No	Parameters	Arthrex ACL TightRope® (K221128) (Primary Predicate)	T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button (Subject Device)	Comments
8.	Design Features	Arthrex ACL TightRope®: 	T-Button®A - Closed button preloaded with UHMWPE adjustable loop  Closed Button  Closed button preloaded with UHMWPE adjustable loop	***SE Analysis 3***

S. No	Parameters	Arthrex ACL TightRope® (K221128) (Primary Predicate)	T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button (Subject Device)	Comments
			T-Button® S - Open button non preloaded with UHMWPE adjustable loop  Open Button 	

S. No	Parameters	Arthrex ACL TightRope® (K221128) (Primary Predicate)	T-Button® A Adjustable Loop UHMWPE Suture PEEK Button, Close Button & T-Button® S Adjustable Loop UHMWPE Suture PEEK Button, Open Button (Subject Device)	Comments
9.	Specifications and Dimensions	• ACL TightRope® RT, double-loaded passing sutures Button - 13mm x 3.3mm x1.5mm (Length x width x Height) Loop Length: 90 mm	• T-button A - Closed button: Button Dimension: 16mm x 7.5mm (Diameter x Height) Loop Length: 90 mm • T-button S - Open button: Button Dimension: 16mm x 7.5mm (Diameter x Height) Loop Length: 90 mm	***SE Analysis** 4*
10.	Single Use/Reuse	Single use	Single use	Similar as predicate device
11.	Shelf Life	5 Years	5 Years	Similar as predicate device
12.	Sterilization	ETO	ETO	Similar as predicate device
13.	Performance Data	• Ultimate load testing • Cyclic displacement	• Pull-Out Testing • Cyclic Loading	Similar as predicate device
14	Safety Data	• Bacterial Endotoxin	• Skin Sensitization, • Intracutaneous reactivity • Material Mediated Pyrogenicity • Acute Systemic Toxicity • In vitro cytotoxicity • Bone Implantation studies • Intramuscular Implantation Study • Bacterial Endotoxin	-

Substantial Analysis

SE Analysis 1
Button Material

The primary predicate **Arthrex ACL TightRope®** button is made of Titanium whereas the reference predicate **ANCHORMAN Tibial Ligament Fixation Device material of construction is PEEK.** The subject device material of construct for button is PEEK (Polyether Ether Ketone) which is equivalent to the reference predicate.

The reference predicate has already proven safety and efficacy of PEEK material in reference to the titanium based button in their K170388 submission.

PEEK is chemically inert and insoluble, has a modulus of elasticity closer to human cortical bone. Hence, PEEK represents a stable and biocompatible material that may address the issues that are present with titanium screws, such as graft damage because of material hardness and interference with imaging. PEEK has poor osseointegration. PEEK has excellent bio-compatibility and biological stability, and is a very favorable implant material.

Also, the bio-compatibility testing of the subject devices has been performed to substantiate the biocompatible nature of the subject device. The summary of the biocompatibility testing performed has been shown in the below table.

Biocompatibility Test	Result
Skin Sensitization (Guinea Pig Maximization Test)	Non-Sensitizer
Intracutaneous Reactivity Test	Non-Reactive
Material Mediated Pyrogenicity	Non-Pyrogenic
Acute Systemic Toxicity Test	Did not Induce any Systemic Toxicity
In vitro Cytotoxicity Test: Elution Method	Non-Cytotoxic
Bone Implantation Studies (PEEK Rods)	Minimal or No Reaction
Bone Implantation Studies (UHMWPE Suture)	Minimal or No Reaction
Intra muscular Implant (PEEK)	Minimal or No reaction

In reference to the above mentioned evidences the difference in the material of construction between the primary predicate and the subject device do not raise any new questions of safety and effectiveness.

SE Analysis 2
Loop Material

The adjustable loop material construct of the primary predicate device (**Arthrex ACL TightRope®)** and the adjustable loop of the T-button®A - Closed button (subject device) is UHMWPE; which are similar.

However, the adjustable loop of the T-button® S - Open button (Subject Device) has Loop and Suture Button. The material of construct of loop is UHMWPE (UHMWPE 100.0%) and Suture Button has a material of construct of Non-absorbable, UHMWPE (UHMWPE ≥ 88.0%) + Additive: Loctite 4014 (≤12.0% in the Suture Button)).

The suture button in the adjustable loop tends to hold the loop, the pull out strength of the suture button in the bench testing has been performed and evaluated, the results are perceptible to define the strength of suture button to hold the loop.

The above mentioned addition of Suture Button in the adjustable loop of the T-button® S - Open button (Subject Device) has no impact on the safety and efficacy of the product.

SE Analysis 3
Design Feature

The **Arthrex ACL TightRope®** and the **ANCHORMAN Tibial Ligament Fixation Device** offers adjustable cortical fixation for cruciate ligament reconstruction. The ACL TightRope® RT comes with the regular button (13mm (L) x 3.3mm (W) x1.5mm (H)) preloaded with adjustable loop and double loaded passing sutures whereas the subject device comes with Open and Closed Button having dimensions (16mm(dia)x 7.5mm (H)). The Closed button is preloaded with UHMWPE adjustable loop and in Open Button the adjustable loop is non preloaded.

The Pull Out Test and the Cyclical Load tests were performed for the primary predicate, reference predicate and the subject device and the results were compared and found equipotent in terms of safety and efficacy irrespective to the material of construction and design.

SE Analysis 4
Specifications 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. 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.

1.7. Summary of Performance Data

The T-Button® Adjustable Loop UHMWPE Suture PEEK Button, Primary Predicate device and Reference Predicate underwent tests to determine their pull-out strength, cyclical loading. Results demonstrated that the T-Button® Adjustable Loop UHMWPE Suture PEEK Button performs statistically equivalent to the predicate device and in addition to mechanical performance testing, biocompatibility testing, sterilization validation, shelf-life, pyrogenicity testing and endotoxin monitoring were also performed to support the demonstration of substantial equivalence.

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 devices Arthrex ACL TightRope® in Intended use, Indications for use, function, Sterilization method, Shelf Life, and operational principles. From the data available we can justify that the T-Button®Adjustable Loop UHMWPE Suture PEEK Button is as safe, and as effective and performs the same indications for use as that of already marketed predicate device identified.