December 28, 2023

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

Re: K230891
Trade/Device Name: SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 28, 2023
Received: November 28, 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,

Sara S. Thompson -S

For

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)*
K230891

Device Name
SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant

Indications for Use *(Describe)*
The SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant is indicated for percutaneous or endoscopic soft tissue procedures which requires usage of a suture retention device. For ex: Meniscus 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.

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1. 510(k) Summary

1.1. Submitter Information:

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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:	27-12-2023

1.2. Device Identification:

Device Trade Name:	SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant
Device Common Name:	Non-Absorbable Suture Retention Device
Classification Name:	Nonabsorbable poly (ethylene terephthalate) surgical Suture
Device Class:	Class II
Regulation Number:	21 CFR 888.3040
Product Code:	MBI

1.3. Predicate Devices:

Table 1 – List of Predicate Device

Device Name	510(k) Number
Smith & Nephew FAST-FIX 360 Meniscal Repair System	K121861

1.4. Device Description

The SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant is an all-inside meniscal repair device with two PEEK non-absorbable polymer implants, preloaded with UHMWPE sutures. SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant is preloaded with USP #3-0 UHMWPE suture whereas SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant XL is preloaded with USP #2-0 suture. The adjustable depth control knob is used to define the needle piercing length in the meniscus prior to deployment of the implant. These meniscal repair devices are available in various needle curvature.

1.5. Intended Use & Indications for Use

Intended Use

The SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as, meniscal repair.

Indications for Use

The SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant is indicated for percutaneous or endoscopic soft tissue procedures which requires usage of a suture retention device. For ex: Meniscus repair.

1.6. Comparison of Technological Characteristics

The fundamental scientific technology, materials of construction and mechanism of operation are similar between the subject device SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant and the predicate device. **Table 2** summarizes the comparison of technological characteristics between the subject and predicate device.

Table 2 – Substantial Equivalence Table

Sl. No	Parameters	Smith & Nephew FAST-FIX 360 Meniscal Repair System (K121861)	SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant (Subject device)
1.	Manufacturer	Smith & Nephew, Inc	Healthium Medtech Limited
2.	Product Code	GAT	MBI
3.	Regulation Number	21 CFR 878.5000	21 CFR 888.3040
4.	Classification	Class II	Class II
5.	Intended Use	The FAST-FIX 360 Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures. The FAST-FIX 360 System is indicated for use in meniscal repairs and allograft transplant procedures. The FAST-FIX 360 System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.	The SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as, meniscal repair.
6.	Material of Construction	Implant - PEEK Suture-UHMWPE with monofilament Polypropylene	Implant - PEEK Suture- UHMWPE
7.	Design Feature	2-peek implants pretied with non-absorbable suture	2-peek implants pretied with non-absorbable suture
8.	Specifications and Dimensions	Implant 1: 5.00 mm X 0.95 mm (LXD) Implant 2: 4.8mmX1.4mmX0.8mm (LXWXH) Delivery Needle: Straight or Curved Suture Size - USP #2-0	Implant 1: 5.50 mm X 0.95 mm (L X D), Implant 2: 6.4(max) mm X 0.95 mm (L X D), Delivery Needle: LEFT, RIGHT, UP, DOWN Suture Size - USP #3-0 Implant 01 XL: 5.50 mm X 1.2 mm (L X D), Implant 02 XL: 6.4(max) mm X 1.2 mm (L X D) Delivery Needle: LEFT, RIGHT, UP, DOWN Suture Size - USP #2-0

Sl. No	Parameters	Smith & Nephew FAST-FIX 360 Meniscal Repair System (K121861)	SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant (Subject device)
9.	Shelf Life	3Years	5 Years
10.	Sterilization Method	EtO	EtO
11.	Performance Data	Pull-out strength, Cyclical loading	Pull-out strength, Cyclical loading
12.	Safety Data	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 SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant and Predicate device underwent tests to determine their pull-out strength and cyclical loading. Results demonstrated that the SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant performs statistically equivalent to the predicate device FAST-FIX 360 meniscal repair system.

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

The SURESTITCH™ UHMWPE Suture PEEK Button Meniscus Repair Implant is substantially equivalent to the predicate devices. Any differences between the subject device and the predicate devices do not raise questions concerning safety and effectiveness.

Based on the indications for use, technological characteristics, and the summary of data submitted, It is determined that the proposed device is substantially equivalent to the currently marketed predicate devices.