November 8, 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: K232886
Trade/Device Name: INFILOOP® Fixed Loop UHMWPE Suture Titanium Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 13, 2023
Received: September 18, 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 (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: 2023.11.08 14:35:52 -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)*
K232886

Device Name
INFILOOP® Fixed Loop UHMWPE Suture Titanium Button

Indications for Use *(Describe)*
The INFILOOP® Fixed Loop UHMWPE Suture Titanium Button is indicated in surgical procedures for soft tissue fixation to the bone. It is used for fixation of tendons and ligaments during orthopaedic reconstruction procedures such as Knee ligament reconstruction which includes anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL), and lateral collateral ligament (LCL).

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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510(k) Summary based on the 21 CFR 807.92

Date Prepared	12 September 2023
510(k) Number	K232886
Submitter	Healthium Medtech Limited 472-D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, India, 560058 Ph: +91 - 80 - 41868000
Contact Person	Pankaj Dawar Deputy General Manager Regulatory Affairs Ph: +91 - 80 – 41868000 pankaj.d@healthiummedtech.com
Name of Device	INFILOOP® Fixed Loop UHMWPE Suture Titanium Button
Common Name	Fixed Loop UHMWPE Suture Titanium Button
Product Code	MBI
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	Conmed Linvatec XO Button™ (Continous Loop) (K070780)-Primary Predicate RIGIDLOOP™ Cortical Fixation System (K130814)-Additional Predicate
Reference Device	No reference device used
Purpose of Submission	Traditional 510(k) is submitted to obtain clearance for the INFILOOP® Fixed Loop UHMPWE suture Titanium Button
Device Description	The use of the INFILOOP® Fixed Loop UHMWPE Suture Titanium Button provides the orthopaedic surgeon a means of accurate fixation in ligament reconstructive surgery of soft tissue to bone fixation. The fixation device allows for arthroscopic ligament reconstruction approaches.
Intended Use/ Indications for Use	The INFILOOP® Fixed Loop UHMWPE Suture Titanium Button is indicated in surgical procedures for soft tissue fixation to the bone. It is used for fixation of tendons and ligaments during orthopaedic reconstruction procedures such as Knee ligament reconstruction which includes anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL), and lateral collateral ligament (LCL).

Comparison of the Technological Characteristics with Predicate Device

S. No	Parameters	Conmed Linvatec XO Button™ (Continous Loop) (K070780) (Primary Predicate)	RIGIDLOOP™ Cortical Fixation System (K130814) (Additional Predicate)	INFILOOP® Fixed Loop UHMWPE Suture Titanium Button (Subject Device)	Comments
1.	Manufacturer	ConMed Linvatec	Medos International SARL	Healthium Medtech Limited	-
2.	Product Code	MBI (Classification Product Code) GAT (Subsequent Product Code)	MBI	MBI	Similar to predicate device
3.	Regulation Number	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040	Similar to predicate device
4.	Classification	Class II	Class II	Class II	Similar to predicate device
5.	Intended Use/ Indications for Use	The Conmed Linvatec XO Button™ with continuos loop is intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or reconstruction of a ligament using soft tissue grafts. Examples of such procedures include anterior cruciate ligament, posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament.	The RIGIDLOOP™ Cortical Fixation System is used for the fixation of soft tissue to bone in orthopedic procedures such as ACL repair	The INFILOOP® Fixed Loop UHMWPE Suture Titanium Button is indicated in surgical procedures for soft tissue fixation to the bone. It is used for fixation of tendons and ligaments during orthopaedic reconstruction procedures such as Knee ligament reconstruction which includes anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL), and lateral collateral ligament (LCL).	Similar to predicate device
6.	Button and Loop Material	Button: Titanium Loop: UHMWPE	Button: Titanium Loop: UHMWPE	Button: Titanium Loop: UHMWPE	Similar to predicate device

S. No	Parameters	Conmed Linvatec XO Button™ (Continous Loop) (K070780) (Primary Predicate)	RIGIDLOOP™ Cortical Fixation System (K130814) (Additional Predicate)	INFILOOP® Fixed Loop UHMWPE Suture Titanium Button (Subject Device)	Comments
7.	Suture Material	• Polyester, USP#5 • UHMWPE, USP#3-4	• UHMWPE, USP#5 • Polyester, USP#5	• UHMWPE, USP#5 • UHMWPE, USP#5	Refer the SE Analysis
8.	Single Use/Reuse	Single Use	Single Use	Single Use	Similar to predicate device
9.	Shelf Life	5 Years	5 Years	5 Years	Similar to predicate device
10.	Sterilization Method	ETO	ETO	ETO	Similar to predicate device
11.	Performance Data	• Pull Out Testing • Cyclical Loading	• Pull Out Testing	• Pull Out Testing • Cyclical Loading	Similar to predicate device
12.	Safety Data	No Data Available	• No Data Available	• Skin Sensitization • Intracutaneous reactivity • Material Mediated Pyrogenicity • Acute Systemic Toxicity • In-vitro cytotoxicity • Bone Implantation • Intramuscular Implantation • Bacterial Endotoxin USP <85> • MRI Compatibility	-

SE Analysis

Predicate devices are preloaded with one UHMWPE suture and one Polyester Suture, whereas the subject device is preloaded with UHMWPE sutures. From the literature study, 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 shows that Pure 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.

Comparison and summary of the technological characteristics

The proposed INFILOOP® Fixed Loop UHMWPE Suture Titanium Button (referred to as the "subjected device") shares similar basic design features and materials of construction for the button and loop when compared to the predicate devices. The specifications and dimensions of the subjected device fall within the range of those of the predicate devices. Minor differences in technological characteristics do not raise any safety or effectiveness concerns.

Comparison and summary of the safety, performance and non-clinical testing data

Verification activities were performed on the implant and its predicates. Testing assessments included biocompatibility, pyrogenicity (both material and bacterial endotoxin) in accordance with USP <85>, sterility, shelf life, pull-out testing, and cyclic loading (as mentioned in the comparison table). The results of performance testing have demonstrated that the proposed devices are suitable for their intended use.

Conclusion

The INFILOOP® Fixed Loop UHMWPE Suture Titanium Button is substantially equivalent to the predicate devices. Any differences between the subject device and the predicate devices do not raised 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.