September 27, 2024

Hyundae Meditech Co., Ltd.
Oh Ju-In
Senior QA Staff
80, Cheongjeong-ro, Jijeong-myeon
Wonju-si, Gangwon 26347
Korea, South

Re: K242571

Trade/Device Name: Secret Line up (FC1938E80 FC1950E90 FC1960E100 FC1970E120 FC1990E150 FC19100E150 FC19100E280 FC19100E420 FC2038E80 FC2050E90 FC2060E100 FC2070E120 FC2090E150 FC20100E170 FC2138G80 FC2150G90 FC2160G100 FC2170G120 FC2190G150 FC21100G170 FCL18100C160 FCL1938E80 FCL1950E90 FCL1960E100 FCL1970E120 FCL1990E150 FCL19100E160 FCL2138G80 FCL2150G90 FCL2160G100 FCL2170G120 FCL2190G150 FCL21100G160 FCRL1870C162 FCRL18100C185 FCRL1970E162 FCRL19100E185 FCHL1960E90 FCHL1970E120 FCHL19100E160 FCW1938E80 FCW1950E90 FCW1960E100 FCW1970E120 FCW1990E150 FCW19100E160 FCW2138G80 FCW2150G90 FCW2160G100 FCW2170G120 FCW2190G150 FCW21100G160); i-Thread (FC1938E80 FC1950E90 FC1960E100 FC1970E120 FC1990E150 FC19100E150 FC19100E280 FC19100E420 FC2038E80 FC2050E90 FC2060E100 FC2070E120 FC2090E150 FC20100E170 FC2138G80 FC2150G90 FC2160G100 FC2170G120 FC2190G150 FC21100G170 FCL18100C160 FCL1938E80 FCL1950E90 FCL1960E100 FCL1970E120 FCL1990E150 FCL19100E160 FCL2138G80 FCL2150G90 FCL2160G100 FCL2170G120 FCL2190G150

Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: August 21, 2024
Received: August 29, 2024

Dear Oh Ju-In:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.09.27 12:06:14 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Secret Line up (FC1938E80
FC1950E90
FC1960E100
FC1970E120
FC1990E150
FC19100E150
FC19100E280
FC19100E420
FC2038E80
FC2050E90
FC2060E100
FC2070E120
FC2090E150
FC20100E170
FC2138G80
FC2150G90
FC2160G100
FC2170G120
FC2190G150
FC21100G170
FCL18100C160
FCL1938E80
FCL1950E90
FCL1960E100
FCL1970E120
FCL1990E150
FCL19100E160
FCL2138G80
FCL2150G90
FCL2160G100
FCL2170G120
FCL2190G150
FCL21100G160
FCRL1870C162
FCRL18100C185
FCRL1970E162
FCRL19100E185
FCHL1960E90
FCHL1970E120
FCHL19100E160
FCW1938E80
FCW1950E90
FCW1960E100
FCW1970E120

FCW1990E150
FCW19100E160
FCW2138G80
FCW2150G90
FCW2160G100
FCW2170G120
FCW2190G150
FCW21100G160);
i-Thread (FC1938E80
FC1950E90
FC1960E100
FC1970E120
FC1990E150
FC19100E150
FC19100E280
FC19100E420
FC2038E80
FC2050E90
FC2060E100
FC2070E120
FC2090E150
FC20100E170
FC2138G80
FC2150G90
FC2160G100
FC2170G120
FC2190G150
FC21100G170
FCL18100C160
FCL1938E80
FCL1950E90
FCL1960E100
FCL1970E120
FCL1990E150
FCL19100E160
FCL2138G80
FCL2150G90
FCL2160G100
FCL2170G120
FCL2190G150
FCL21100G160
FCRL1870C162
FCRL18100C185
FCRL1970E162
FCRL19100E185
FCHL1960E90
FCHL1970E120
FCHL19100E160
FCW1938E80
FCW1950E90
FCW1960E100
FCW1970E120

FCW1990E150
FCW19100E160
FCW2138G80
FCW2150G90
FCW2160G100
FCW2170G120
FCW2190G150
FCW21100G160)

Indications for Use *(Describe)*

Secret Line up and i-Thread (Sterile single use absorbable polydioxanone suture with needle) comprised of dyed polydioxanone suture with a sterile needle. It is indicated for use in soft tissue approximation where use of absorbable suture is appropriate. The suture is not intended for body cavity applications, nor is it intended for lifting and supporting tissues; it is intended for dermatological use only.

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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510(k) Summary

(Special 510k-K242571)

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date prepared: August 21, 2024

I. SUBMITTER

Submitter's Name	Hyundae MediTech Co.,Ltd.
Submitter's Address	80, Cheongjeong-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Republic of Korea
Submitter's Telephone	+82-70-4490-2604
Contact person	Ju-in Oh / Quality management dept / Assistant manager
	qa@hyundaemed.co.kr
Telephone	+82-70-4490-2604
Fax:	+82-33-734-3065

II. DEVICE

Trade/proprietary Name	Secret Line up / i-Thread
Common or Usual Name	Absorbable Polydioxanone Suture with Needle
Regulation Name	Absorbable Polydioxanone Surgical Suture
Regulation Number	21 CFR 878.4840
Product Code	NEW
Regulatory Class	Class II

III. PREDICATE DEVICE

Primary Manufacturer	Hyundae MediTech Co.,Ltd.
Device Name	Secret Line up / i-Thread
510(k) Number	K240389
Regulation Name	Absorbable Polydioxanone Suture with Needle
Regulation Number	21 CFR 878.4840
Product Code	NEW
Regulatory Class	Class II

IV. DEVICE DESCRIPTION

Secret Line up and i-Thread (Sterile single use absorbable polydioxanone suture with needle) consist of a cannula type needle which is straight and hollow (pre-loaded on the suture), a needle cap, a hub, a sponge and polydioxanone (PDO) suture which is sterilized by ethylene oxide (EO) gas. The pigment for the violet dye is D&C Violet No.2.

PDO Sutures are characterized by their bidirectional barbs along the long axis of the monofilament. The bi-directional barbs of barbed suture are precisely lodged in tissue, making it feasible to anchor in the tissue and prevent movement in both directions without the need for a surgical knot. As a result, the barbed suture improves the effectiveness of treatment.

V. INDICATIONS FOR USE

Secret Line up and i-Thread (Sterile single use absorbable polydioxanone suture) comprised of dyed polydioxanone suture with a sterile needle. It is indicated for use in soft tissue approximation where use of absorbable suture is appropriate. The suture is not intended for body cavity applications, nor is it intended for lifting and supporting tissues; it is intended for dermatological use only.

VI. SUBTANTIALLY EQUIVALENT (SE) COMPARISON CHART

Subject device is substantially equivalent to Secret Line up / i-Thread (K240389).
The following comparison table is presented to demonstrate substantial equivalence.

Category	Subject Device	Predicate Device	Remark
510(k) number	K242571 (special 510k)	K240389	Not applicable
Product code	NEW	NEW	SE
Regulation number	21 CFR 878.4840	21 CFR 878.4840	SE
Class	II	II	SE
Device trade name (Brand name)	Secret Line up and i-Thread (Absorbable Polydioxanone Surgical Suture)	Secret Line up and i-Thread (Absorbable Polydioxanone Surgical Suture)	SE
Common name	Absorbable polydioxanone suture with needle	Absorbable Polydioxanone Suture with Needle	SE
Manufacturer	Hyundae MediTech Co.,Ltd.	Hyundae MediTech Co.,Ltd.	SE

Device description	Secret line up, i-Thread (Sterile single use absorbable polydioxanone suture with needle) consist of a cannula type needle which is straight and hollow (pre-loaded on the suture), a needle cap, a hub, a sponge and polydioxanone (PDO) suture which is sterilized by ethylene oxide (EO) gas. The pigment for the violet dye is D&C Violet No.2.	Secret line up, i-Thread (Sterile single use absorbable polydioxanone suture with needle) consist of a cannula type needle which is straight and hollow (pre-loaded on the suture), a needle cap, a hub, a sponge and polydioxanone (PDO) suture which is sterilized by ethylene oxide (EO) gas. The pigment for the violet dye is D&C Violet No.2.	SE
Indication for use	Secret Line and i-Thread (Sterile single use absorbable polydioxanone suture) comprised of dyed polydioxanone suture with a sterile needle. It is indicated for use in soft tissue approximation where use of absorbable suture is appropriate. The suture is not intended for body cavity applications, nor is it intended for lifting and supporting tissues; it is intended for dermatological use only.	Secret Line and i-Thread (Sterile single use absorbable polydioxanone suture) comprised of dyed polydioxanone suture with a sterile needle. It is indicated for use in soft tissue approximation where use of absorbable suture is appropriate. This device is not intended for body cavity applications or lifting and supporting tissues and is intended for dermatological use only.	SE
Sterilization method	E.O. sterilization (SAL: 1.0×10^{-6})	E.O. sterilization (SAL: 1.0×10^{-6})	SE
Stability time	2 years	2 years	SE
Suture material	Polydioxanone	Polydioxanone	SE
Configuration	PDO Suture and Needle. (Pre-loaded with a hollow needle and is not swaged.)	PDO Suture and Needle. (Pre-loaded with a hollow needle and is not swaged.)	SE
Suture color	Dyed suture (violet)	Dyed suture (violet)	SE
Suture size (USP)	2-0, 0, 2	2-0, 0, 2	SE
Suture length	80, 90, 100, 120, 150, 160, 162, 185, 170, 280, 420 mm	150, 160 mm	Similar - As the predicate device has various ranges of suture lengths compared to subject device.
Suture type	Cog (barb) type	Cog (barb) type	SE
Barb angle	50 – 80 degrees	50 – 80 degrees	SE
Suture composition	Polydioxanone, Dyed with D&C Violet No.2	Polydioxanone, Dyed with D&C Violet No.2	SE

Needle material	Stainless steel	Stainless steel	SE
Absorbable / Non-Absorbable	Absorbable	Absorbable	SE
Braided / Monofilament	Monofilament	Monofilament	SE
Barb type	Bi-directional	Bi-directional	SE
Biocompatible	Yes	Yes	SE
Material of components that come into patient contact	1) Needle: Stainless steel 2) Suture: Polydioxanone	1) Needle: Stainless steel 2) Suture: Polydioxanone	SE
Anatomical location	Soft tissue (Skin, Dermal or Sub-dermal tissue)	Soft tissue (Skin, Dermal or Sub-dermal tissue)	SE
Intended population	Adults, but inappropriate for elderly population	Adults, but inappropriate for elderly population	SE
Performance test conducted	1) Suture : Length, Diameter, Tensile strength, Barb-Holding, Needle attachment strength 2) Needle : Length, Outer diameter, Bending(elasticity), Flexural strength, Pulling out	1) Suture : Length, Diameter, Tensile strength, Barb-Holding, Needle attachment strength 2) Needle : Length, Outer diameter, Bending(elasticity), Flexural strength, Pulling out	SE
Performance test (Animal testing)	In Vivo testing in Sprague-Dawley Rat – Absorption, Barb Holding force and Tensile Strength over time	In Vivo testing in Sprague-Dawley Rat – Absorption, Barb Holding force and Tensile Strength over time	SE
Performance testing result	Pass	Pass	SE
Single use	Yes	Yes	SE
Reusable component	N/A	N/A	SE
Nano technology	N/A	N/A	SE
Clinical test	Not required	Not required	SE
Despite the differences, the test results submitted in this 510(k) show that the subject device is substantially equivalent to the predicate devices in safety and effectiveness. In almost all aspects, the subject device is substantially equivalent in its capacity and function to the predicate device.			

VII. DESCRIPTION FOR DIFFERENCE

The Subject device has the same intended use as that of the predicate device. There is minor difference between the two devices where it is indicated “similar”, in all other cases it is seen that the subject stays as “Substantial Equivalent” to that of the predicate device characteristics.
Differences observed from the above table are with respect to suture length. Despite this difference, it is

witnessed from the test results submitted as part of 510(k) that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness and there is no difference in terms of intended clinical application. Additionally, the subject device is substantially equivalent to the capacity and function of the predicate device.

VIII. PERFORMANCE TESTING

Performance testing was conducted on the subject device to prove that all the design specifications are substantially equivalent to the predicate device. The test results of the subject device are demonstrated in accordance with the following FDA and international standards:

* FDA Guidance on Surgical Sutures – Performance Criteria for Safety and Performance Based Pathway
* Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff
* USP 43-NF38 <861> Sutures – Diameter
* USP 43-NF38 <871> Sutures – Needle Attachment
* USP 43-NF38 <881> Sutures – Tensile Strength
* USP 37-NF 32: 2014 – Dimension test
* ASTM F1874-98 9 bending test
* lSO 10993-1:2020, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process
* lSO 10993-7:2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Results
* ISO 11135:2014, Sterilization of Healthcare Products Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
* ISO 10993:2009, Biological Evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
* ISO 10993:2017, Biological Evaluation of medical devices – Part 4: Selection of Test for Interaction with Blood, Annex D.5 Hemolysis Testing
* ISO 10993:2017, Biological Evaluation of medical devices – Part 11: Test for systemic Toxicity, Annex G – Information on material mediated pyrogens
* ISO 10993:2021, Biological Evaluation of medical devices – Part 23: Tests for Irritation, 7.3 Animal Irritation test by Intracutaneous (Intradermal) administration
* ISO 10993:2010, Biological Evaluation of medical devices – Part 10: Test for Irritation and Skin Sensitization, 7.5 Guinea Pig Maximization Test
* ISO 10993:2021, Biological Evaluation of medical devices – Part 12: Sample preparation and reference materials
* ISO 10993:2016, Biological Evaluation of medical devices – Part 6: Test for local effects after implantation
* ISO 10993:2014, Biological Evaluation of medical devices – Part 3: Test for Genotoxicity, Carcinogenicity and Reproductive toxicity, 5. Genotoxicity test
* ISO 14971:2019, Medical Devices - Risk Management for Medical Devices.

Furthermore, the following non-clinical bench tests were performed on the subject device:
* Measurement (Outside diameter, Length, hub)
* Bending test
* Barb Holding strength
* Flexural test
* Pulling out (or) Extraction Test

IX. ANIMAL STUDIES

The purpose of the in vivo study is to evaluate the biodegradability of the Sterile Single Use Absorbable Polydioxanone Suture by comparing the two models in “absorption”, “Tensile strength test” and “Barb holding strength test” by the time.

X. CLINICAL STUDIES

As per the Guidance document "Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff”, no Clinical Studies were performed nor required.

XI. SUMMARY

Based on the indications for use and safety and performance testing, the subject device meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use.

The conclusions drawn from the non-clinical and biocompatibility test reports to demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device.