July 24, 2026

Medical Impact
Hanna Kim
Quality Management Representative
2314, 2214, 2217~2219, 122, Jomaru-Ro 385beon-Gil
Bucheon-Si
Gyeonggi-Do, 14556
Republic Of Korea

Re: K253541
Trade/Device Name: EZ-Close™ (EZ Close Port Site Closing Device, EZ Close MAX Port Site Closing Device, EZ Close II Port Site Closing Device)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, OCW
Dated: June 15, 2026
Received: June 16, 2026

Dear Hanna Kim:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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)*

K253541

Device Name

EZ-Close™
(EZ Close Port Site Closing Device,
EZ Close MAX Port Site Closing Device,
EZ Close II Port Site Closing Device)

Indications for Use *(Describe)*

The EZ-Close™ is indicated to close perforated peritoneum and fascia for trocar insertion during laparoscopic surgery.

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
(K253541)

Contact Details		
Applicant Name	MEDICAL IMPACT	
Applicant Address	2314, 2214, 2217~2219, 122, Jomaru-ro 385beon-gil, Bucheon-si Gyeonggi-do 14556 Korea, South	
Applicant Contact Telephone	82 02 6225 3300	
Applicant Contact	Ms. Hanna Kim	
Applicant Contact Email	hnkim1217@medicalimpact.co.kr	
Date Prepared	July 24, 2026	
Device Name		
Device Trade Name	EZ-Close™ (EZ Close Port Site Closing Device, EZ Close MAX Port Site Closing Device, EZ Close II Port Site Closing Device)	
Common Name	Endoscopic tissue approximation device	
Classification Name	Laparoscope, General & Plastic Surgery	
Regulation Number	876.1500	
Product Code(s)	GCJ, OCW	
Legally Marketed Predicate Devices		
Predicate #	Predicate Trade Name	Product Code
K132362	WECK EFx Endo Fascial Closure System	GCJ, OCW, HCF
Reference Devices		
510(k) #	Reference Trade Name	Product Code
K142903	NeoClose	GCJ
K161629	CRYLREX®	GAM

Device Description Summary

EZ-Close™ is intended to be used to suture the peritoneum and fascia at the trocar insertion site during laparoscopic procedures. It consists of a body, needles, and a cartridge containing PGLA absorbable suture. All components of the device are made of materials that have passed ISO 10993 biocompatibility testing.

The primary distinction between the EZ Close Port Site Closing Device, EZ Close MAX Port Site Closing Device, and EZ Close II Port Site Closing Device is the size of the device. EZ Close and EZ Close MAX are intended for use with trocars larger than 10 mm, while EZ Close II is designed for use with trocars larger than 8 mm in patients undergoing laparoscopic surgery.

To achieve the intended clinical benefit, each product must be used in combination as follows:
- EZ Close Port Site Closing Device: Uses Body & Needle (EZ01) with Cartridge (EZ02) together.
- EZ Close MAX Port Site Closing Device: Uses Body & Needle (EZ03) with Cartridge (EZ04) together.
- EZ Close II Port Site Closing Device: Uses Body & Needle (EZ05) with Cartridge (EZ06) together.

The absorbable suture (Neosorb) conforms to USP 0 specifications, except for diameter, in accordance with international standards:
<MAXIMUM SUTURE OVERSIZE IN DIAMETER (mm) FROM U.S.P.>

- U.S.P. Suture Size Designation : 0
- Maximum Oversize : 0.056mm

The absorbable suture is coated with poly (glycolideco-lactide) (30/70) and calcium stearate and is provided dyed (D&C Violet No.2). The absorbable suture gradually loses its tensile strength through hydrolysis, resulting in final absorption. The copolymer is broken down into glycolic acid and lactic acid during the hydrolysis process and is absorbed and metabolized in the body. The tensile strength of the suture maintains on average 65% of its original tensile strength two weeks after implantation.

During laparoscopic surgery, one to three (or more) port sites are typically created, and the surgeon determines whether each port should be sutured. This product can be used to suture multiple ports within a single procedure using one Body & Needle (EZ01, EZ03, or EZ05) and up to three Cartridges (EZ02, EZ04, or EZ06) for the same patient. As a single-use disposable device, the product must be discarded immediately after use, and no resterilization is performed.

Intended Use/Indications for Use

The EZ-Close™ is indicated to close perforated peritoneum and fascia for trocar insertion during laparoscopic surgery.

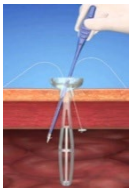
Indications for Use Comparison

This product is a device used to close incisions during laparoscopic surgery and is intended for patients who have abdominal incisions resulting from laparoscopic surgery. The indications for use and target patients for this product are the same as for predicate devices.

Technological Comparison

We compared the device with the predicate device in various aspects using the Substantial Equivalence Comparison Table. While there were differences in the categories of Appearance, Anatomical Site, Applicable Trocar Size, Sterilization Method, and Suture Included or not, none of these differences affected the safety or effectiveness of the product.

1. Body and Needle

Device / Category	Subject Device	Predicate Device	Reference Device	Equivalence Discussion
	EZ-Close™	WECK EFx Endo Fascial Closure System	NeoClose	
510(K) No. (#)	K253541	K132362	K142903	-
Manufacturer	Medical Impact	Teleflex Medical, Inc.	neoSurgical Ltd.	-
Device Classification	Class II	Class II	Class II	Same
Product Code	GCJ, OCW	OCW, GCJ, HCF	GCJ	Same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Same
Classification Name	Endoscope and accessories	Endoscope and Accessories	Endoscope and Accessories	Same
Appearance				Different
Indications for Use	The EZ-Close™ is indicated to close perforated peritoneum and fascia for trocar insertion	The WECK EFx Endo Fascial Closure System has application in laparoscopic procedures for	neoClose is intended to facilitate the delivery of absorbable AutoAnchors through soft tissues of the	Same

	during laparoscopic surgery.	approximation of tissue and percutaneous suturing for closing incision sites.	body during endoscopic/laparoscopic surgery.	
Target patient Population	Patient under laparoscopic surgery	Patient under laparoscopic surgery	Patient under laparoscopic surgery	Same
Target User Population	It is to be used only by surgeons trained in endoscopic/laparoscopic surgery.	Clinician who is qualified to participate a laparoscopic surgery.	It is to be used only by surgeons trained in endoscopic/laparoscopic surgery.	Same
Target anatomical location	Fascial and abdominal wall	Abdominopelvic (abdominal) cavity	Abdominal wall	Similar
Where Used	Hospital O.R. room	Hospital O.R. room	Hospital O.R. room	Same
Contraindications	Do not use where laparoscopic technique is generally contraindicated. Sutures are absorbed within 56 to 70 days, so do not use them in areas that require long-term tissue sutures.	Do not use where laparoscopic techniques are generally contraindicated	No information	Same
Applicable Trocar size	10 ~ 15 mm, 8 ~ 10 mm (EZ Close II: when adapter is removed)	10 ~ 15 mm	8 ~ 15 mm	Similar
Performance	We verified the following specifications: Material Verification, Visual Inspection (Appearance, Defects, and Cleanliness), Dimensional Inspection, Mechanical Inspection (Operation, Fastening, and Durability) In addition, the sutures were tested for the following specifications: Tensile Strength, Suture Ring Burst Strength, Residual Tensile Strength	The test specifications are as follows: Material Verification, Visual Inspection for Defects and Cleanliness, Dimensional Inspection, Mechanical Inspection, Suture Retention, Destructive Testing of Failure Modes	Bench Testing was conducted for the neoClose AutoAnchor Pack to demonstrate that it is at least as safe and effective as the predicate device.	Different
Biocompatibility	A biological evaluation was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA. The cartridge (with suture) is considered a permanent implant, while the Body and needle is considered tissue contacting for a duration that is less than 24 hours.	All patient contacting materials are in compliance with ISO 10993-1.	A biological evaluation was conducted for the neoClose AutoAnchor Pack in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA.	Same

			The neoClose AutoAnchor is considered a permanent implant, while the neoClose Driver is considered tissue contacting for a duration that is less than 24 hours.	
Sterilization Method	Ethylene Oxide	Radiation	Ethylene Oxide	Different
Assurance Level	SAL 10^{-6}	SAL 10^{-6}	No information	Same
Reprocessing	Single use only; not reprocessable	Single use only; not reprocessable	Single use only; not reprocessable	Same
Suture Included	Includes Suture - Absorbable suture (PGLA)	Suture Not Included	Includes Suture - Absorbable suture (PGA) - AutoAnchor: PGLA	Different

2. PGLA suture

Device / Division	Subject Device	Reference Device	Equivalence Discussion
	PGLA suture	CRYLREX®	
510(K) No. (#)	XXXXXXX	K161629	-
Manufacturer	Medical Impact	SM ENG CO., Ltd	-
Device Classification	-	Class II	-
Product Code	-	GAM	-
Regulation No.	-	21 CFR 878.4493	-
Design			-
Indications for Use	The EZ-Close™ is indicated to close perforated peritoneum and fascia for trocar insertion during laparoscopic surgery.	CRYLREX® is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.	-
Raw Suture Material	Neosorb	Neosorb	Same
Manufacturer of Raw Suture Material	Samyang Biopharmaceuticals Corporation	Samyang Biopharmaceuticals Corporation	Same
Final Material Composition	90% glycolide and 10% Llactide (PGLA)	90% glycolide and 10% Llactide (PGLA)	Same
Coating material	Poly(glycolide-co-lactide) (30/70)+ Calcium Stearate	Poly(glycolide-co-lactide) (30/70)+ Calcium Stearate	Same
Color (Colorant)	Dyed (D&C Violet No.2)	Undyed (natural) or Dyed (D&C Violet No.2)	Same
Absorbable/ Nonabsorbable	Absorbable	Absorbable	Same

Braided/ Monofilament	Braided	Braided	Same
Suture Size	The proposed device is available in a single size (USP 0), which corresponds to the size identified in the currently recognized United States Pharmacopeia, except for diameter.	The proposed device is available in 8-0, 7-0, 6-0,5-0, 4-0,3-0,2-0, 0, 1 and 2, which are the sizes identified in the currently recognized United States Pharmacopoeia except for diameter	Similar
Length of Suture	60cm (EZ02, EZ06), 70cm (EZ04)	20cm, 30cm, 45cm, 60cm, 70cm, 75cm, 90cm, 100cm, 125cm, 140cm, 150cm, 250cm,	Similar
Diameter of Suture	Oversize	Oversize	Same
Tensile strength	The tensile strength complies with the requirements of USP.	The tensile strengths comply with the tensile requirement listed in USP 35 <881> Tensile Strength	Same
Biocompatibility	A biological evaluation was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA. The suture is considered a permanent implant.	A biological evaluation was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA. The suture is considered a permanent implant.	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Same
Single Use	Yes	Yes	Same

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

A biological evaluation was conducted for the EZ-Close™ in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA.

The absorbable suture included in the cartridge are considered permanent implant, while the body and needles are considered tissue contacting for a duration that is less than 24 hours.

Bench Testing

Bench Testing was conducted for the EZ-Close™ and the absorbable suture to demonstrate.

The absorbable sutures meet the requirements of the "Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff." Sutures were tested, except for diameter, according to USP standards. Since the absorbable sutures we provide are supplied in cartridge form, needle attachment tests were not performed as they are not applicable.

Additionally, we also performed operation, fastening and durability test, suture ring burst strength, and residual tensile strength tests to demonstrate that our products perform as intended.

Sterilization & Packaging/Shelf-Life

Sterilization validation was performed in accordance with ANSI/AAMI/ISO 11135:2014/A1:2018.

Packaging validation was performed in accordance with ASTM F1980-16.

No clinical testing was required.

The EZ-Close™ is considered substantially equivalent to the predicate device. It has the same intended use and does not raise new questions regarding safety or effectiveness. It is considered at least as safe and effective as the predicate device when used in accordance with the Instructions for Use.