August 31, 2023

Health Value Creation BV, trading as Corporis Medical
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consluting Srl
Piazza Albania 10
Rome, 00153
Italy

Re: K213271
Trade/Device Name: MedicloseTM System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCW, GCJ, HCF
Dated: June 15, 2023
Received: June 16, 2023

Dear Roger Gray:

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,

David Krause -S

David Krause, Ph.D.
Deputy Director
OHT4, Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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)*

K213271

Device Name

Mediclose™ System

Indications for Use *(Describe)*

The Mediclose™ System is a single-use suturing device indicated for approximation of tissues and percutaneous suturing of port-site fascia wounds following 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.

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510(k) Summary

510(k) Reference:	K213271
Device Name:	Mediclose™ System
Type of 510(k) submission:	Traditional
Date of submission:	26 August 2023
510(k) Owner and Submitter:	Health Value Creation BV, trading as Corporis Medical Oxfordlaan 55 6229 EV Maastricht The Netherlands
Owner/Operator Reg. Number:	Not yet registered
510(k) Application Correspondent:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome, Italy
Phone: **Email:**	+39 06 578 2665 rgray@donawa.com
FDA Product Code:	OCW, GCJ, HCF
FDA Regulation Number:	21 CFR 876.1500
FDA Classification Name:	Endoscopic Tissue Approximation Device
Classification Panel:	Gastroenterology and Urology
Common Name:	Endoscopic Tissue Approximation Device
FDA Classification:	Class II
Submission Type:	510(k)

Predicate Device:
The predicate device selected for comparison with the Mediclose™ is:

Predicate Device:	WECK EFX Endo Fascial Closure System
Sponsor:	Teleflex Medical, Inc.
510(k) Number:	K132362
Clearance Date:	8 October 2013
FDA Product Code:	OCW, GCJ, HCF
Classification Name:	Endoscopic tissue approximation device
Regulation No:	21 CFR 876.1500
Class:	II

Device Description:
The Mediclose™ System is an Automatic Trocar Closure (ATC) device supplied with one or more Mediclose™ Adaptors, supplied sterile for single use. The combination of the Mediclose™ Device and one Mediclose™ Adaptor results in a minimally invasive surgical system which aids surgeons in closing trocar wounds following a laparoscopic procedure. In laparoscopic surgery, trocars are used to gain access to the body in a minimally invasive way. This means that these procedures are performed through incisions of approximately 12 mm, compared to traditional open surgery which needs a large wound across the abdomen. The Mediclose™ Device is available in one size and configuration, designed for single-handed use, to which each of three Mediclose™ Adaptors can be fitted, at the user's option, depending on the make/model of trocar being used.

The Mediclose™ System is intended to pass a suture through the soft-tissue layer (fascia) of a trocar wound after laparoscopic surgery. This is done with the end-goal of closing the trocar-induced wound by pulling needles through the fascia and subsequently closing the wound.

The Mediclose™ System has two items:

- The Mediclose™ Device, which incorporates the suture and needle set;
- The Mediclose™ Adaptor, three color-coded models are available separately from the Mediclose™ Device which are compatible with a specific brand/model of 12 mm trocar sleeves that are legally cleared for marketing in the USA, viz:
    - Ethicon EndoPath
    - Covidien VersaOne
    - Applied Medical Kii

The Mediclose™ Device also contains a needle-suture set manufactured by Assut Europe composed of two straight cylindrical needles attached to Glicofil Lac, a braided, coated, violet PGLA absorbable suture. The suture and needles are mounted into the device at the time of manufacture, making it ready to use upon opening the packaging.

Indications for Use:
The Mediclose™ System is a single-use suturing device indicated for approximation of tissues and percutaneous suturing of port-site fascia wounds following laparoscopic surgery.

Comparison of Technological Characteristics Between the Subject Device and Predicate Device:
The following table provides a comparison of the technological characteristics of the subject device and selected predicate device.

Comparison of Technological Characteristics			
Characteristic	**Subject device**	**Predicate device**	**Similarity**
Device name	Mediclose™ System	WECK EFX	N/A
510(k) Sponsor	Health Value Creation BV, trading as Corporis Medical, Netherlands	Teleflex Medical, Inc., USA	N/A
510(k) Reference	K213271	K132362	N/A
Clearance Date	This submission	8 October 2016	N/A
FDA Product Code	OCW, GCJ, HCF	OCW, GCJ, HCF	Same
FDA Classification Name	Endoscopic tissue approximation device	Endoscopic tissue approximation device	Same
FDA Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Device description	A minimally invasive surgical device, which aids surgeons in closing trocar wounds following a laparoscopic procedure.	Designed to facilitate placement and withdrawal of suture loops to perform repair port entry punctures.	Same
Indications for use	The Mediclose™ System is a single-use suturing device indicated for approximation of tissues and percutaneous suturing of port-site fascia wounds following laparoscopic surgery.	The WECK EFX Endo Fascial Closure System has application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.	Equivalent
Use environment	Operating room, sterile field	Operating room, sterile field	Same
Patient population	Patients undergoing abdominal laparoscopic surgery	Patients undergoing abdominal laparoscopic surgery	Same
Sterile?	Yes, by ethylene oxide, SAL 10^{-6}	Yes, by radiation, SAL 10^{-6}	Different
Sterility Standard	ISO 11135: 2014/AMD 1:2018	Unknown	N/A
Single use?	Yes	Yes	Same
Shelf Life	12 months	Unknown	N/A

Comparison of Technological Characteristics			
Characteristic	**Subject device**	**Predicate device**	**Similarity**
Mechanism of Action	Manual manipulation and energy from spring release	Manual manipulation	Similar
Deployed through Trocar Sleeve?	Yes	No, deployed through incision after removal of trocar sleeve	Different
Compatible with different Trocar Sleeves?	Yes, by means of mechanical adaptors	Unnecessary – device not deployed through trocar sleeve	Different
Compatible Wound Size	Wounds made by 12 mm trocars and maintained by 12 mm trocar sleeves	Wounds made by 10/12 or 15 mm trocars (2 x models available with 'pilot guides')	Different
Integral Needles?	Yes	Yes	Same
Suture Type/Size	PGLA Size 0 Braided Suture	PGLA Size 0 Braided Suture	Same
Suture pre-loaded?	Yes	No, suture must be loaded prior to use	Different
Separate suture passer?	No – needles and suture are integral to the device	Yes	Different
Prescription device?	Yes, Rx only	Yes, Rx only	Same
Biocompatibility Standards	ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017	Unknown	N/A
Bacterial Endotoxin Test	LAL test EP 2018: 20614	Unknown	
Bench Tests	Mechanical test of critical items Assembly tensile integrity tests Adaptor tensile integrity tests Suture tensile strength Suture knot pull strength Needle retention force Operating button spring resistance Passage through trocar tubes Transportation test	Mechanical function test Suture retention test Destructive testing	Similar
Animal Tests	Porcine cadaver tests *In vivo* porcine tests	Unknown	N/A
Other Pre-clinical Tests	Human tissue fascia tests	Unknown	N/A
Usability Assessment	Yes	Unknown	N/A

The subject device and the predicate device have many identical or similar properties or features. The differences that exist and are identified in the above table include:

- Sterilization method
- Use with/without trocar sleeve
- Compatibility with trocar systems
- Suture loading
- Suture passer

None of the identified differences introduce new aspects of safety or effectiveness.

Summary of non-clinical testing:
Non-clinical testing of the Mediclose™ System includes:

Non-clinical testing summary				
Test Purpose	**Standard**		**Acceptance criteria**	**Result**
Sterilization validation	ISO 11135:2020 [1]	5 samples	Sterile after half ETO cycle	Pass
Shelf life validation:	ISO 11607-2:2006 [2] See a) to e) below			
a) Transportation test	ISTA 3A:2018 [3]	1 x sample	Packaging is fully functional and undamaged	Pass
b) Sterile pack seal integrity	ASTM F1929-15 [4]	3 samples after ISTA 3A test	No dye penetration	Pass
c) Sterile pack seal strength	EN 868-5:2019 [5]	24 samples after ISTA 3A test	>1.5 N/15mm	Pass
d) Suture needle/thread strength	USP <881> [6]	5 samples after ISTA 3A test	Average >14.7 N Single result >4.41 N	Pass Pass
e) Suture knot pull strength	USP <881>	10 samples after ISTA 3A test	Average >38.2 N	Pass
Biocompatibility:	See a) to f) below:			
a) Cytotoxicity	ISO 10993-5:2009 [7]	Optical density	≥70% of the control mean % viability	Pass
b) Sensitization	ISO 10993-10:2010 [8]	Kligman maximization 35 guinea pigs	Positive response in <10% of tests animals	Pass
c) Intracutaneous Reactivity	ISO 10993-10:2010	3 white rabbits	[Test article mean] – [Control mean] ≥ 1.0	Pass
d) Acute systemic toxicity	ISO 10993-11:2017 [9]	10 male mice	Absence of toxic reaction after 72 hours	Pass
e) Material mediated Rabbit pyrogen	ISO 10993-11:2017	4 white rabbits	Temperature rise >0.5 degC	Pass
f) LAL bacterial endotoxicity	EP 01/2018: 20614 [10]	3 samples	<0.5 EU/ml	Pass
Mechanical tests:	See a) to h) below			
a) Mediclose joint tensile tests	Internal test protocol	3 samples each, upper and lower joint	>15 N	Pass
b) Mediclose folding part to handle tensile	Internal test protocol	2 samples	>30 N	Pass
c) Mediclose folding part to handle compression	Internal test protocol	3 samples	>30 N	Pass
d) Needle retention force	Internal test protocol	5 samples average	>15 N <30 N	Pass
e) Mediclose assembly tensile	Internal test protocol	3 samples	>30 N	Pass
f) Adaptor security tensile	Internal test protocol	3 samples per adaptor type	>30 N	Pass
g) Operating button spring resistance	Internal test protocol	3 samples	<23.3 N	Pass
h) Device passage through trocar sleeve	Internal test protocol	3 samples per adaptor type	Unrestricted passage	Pass
Performance tests in porcine model with pneumoperitoneum	Internal test protocol	44 Mediclose units	No functional failures	Pass
Performance tests in human fascia model	Internal test protocol	20 Mediclose units	No functional failures	Pass

Summary of clinical information
No clinical testing was submitted, referenced, or relied on for the subject device.

Conclusion:
The subject and predicate devices have very similar intended uses and fundamental technological characteristics. Any differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The conclusions drawn from the non-clinical testing demonstrate that the subject device is as safe, as effective, and performs as well or better than the legally marketed predicate device K132362.

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[1] Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

[2] Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes

[3] Packaged products for parcel delivery system shipment 70 kg or less

[4] Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

[5] Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

[6] Tensile strength

[7] Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

[8] Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

[9] Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

[10] Bacterial endotoxins