July 18, 2024

Medscope Biotech Co., Ltd.
Waine Su
Sr. Regulatory Affairs Specialist
2F, No. 8, Keyi Street, GuangYuan Technology Park,
Zhunan Town, Miaoli County, 35059
Taiwan

Re: K221495
Trade/Device Name: SOLID CLIP™ Single Use Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: August 3, 2023
Received: August 3, 2023

Dear Waine Su:

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.07.18 11:44:44 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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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)*
K221495

Device Name
SOLID CLIP Single Use Clip Applier

Indications for Use *(Describe)*
The SOLID CLIP Single Use Clip Applier is intended for patients undergoing laparoscopic surgical procedures and can achieve dissection and ligation of blood vessels and other tubular structures for radiographic marking.

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.

510(k) Summary

K221495

1. SUBMITTER

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Date Prepared：July 08, 2024

2. DEVICE

Device Name	SOLID CLIP™ Single Use Clip Applier
Trade/Proprietary Name	SOLID CLIP™
Common Name	Clip Applier
Regulation Number	21 CFR 878.4300
Regulation Name	Implantable clip
Regulatory Class	Class II
Panel	General and Plastic Surgery
Product Code	FZP

3. PREDICATE AND REFERENCE DEVICES

Predicate Device	Endo Clip™ II Clip Applier, K143644
Company Name	Covidien
Reference Device	ENDO CLIP™ III 5mm Clip Applier, K121194
Company Name	Covidien
Regulation Number	21 CFR 878.4300
Product Code	FZP

4. DEVICE DESCRIPTION

The SOLID CLIP™ Single Use Clip Applier is a sterile, single patient use device designed for an appropriately sized trocar sleeve or larger sized trocar sleeve with the use of a converter. It consists of a shaft with an outer diameter of 10 or 5 mm and length of 33 cm, a jaw for forming ligating clips, a pistol handle, an actuation trigger, a 360 degrees rotational knob, and a clip counter.

The shaft with outer diameter 10 mm was preloaded 10, 15, 20 ML (Medium-Large) or 10, 15 L (Large) titanium clips, outer diameter 5 mm shaft only preloaded 10, 15 ML (Medium-Large) titanium clips. Squeezing the trigger places a titanium clip in the jaws and closes the jaws to form the clip on the occlusion of the vessel or tubular structure.

The design of SOLID CLIP™ Single Use Clip Applier provides secured placement of the clip to the targeted vessel and enables the surgeon to apply the clips during a laparoscopic procedure without the need for withdrawing and reinserting the device each time a clip is put in place and closed.

Series	Model No.	Shaft Length (mm)	Shaft Diameter (mm)	Clip Size	Clip Q'ty.	Clip Dimension (mm) 		
						W	H	L
CA16	CA165	330	10	L	10	4.5	9.8	11
	CA166	330	10	L	15	4.5	9.8	11
	CA167	330	10	ML	15	4.5	7.8	9
	CA168	330	10	ML	20	4.5	7.8	9
	CA169	330	10	ML	10	4.5	7.8	9
CA56	CA567	330	5	ML	10	3.5	8.2	9
	CA568	330	5	ML	15	3.5	8.2	9

5. INDICATIONS FOR USE

The SOLID CLIP™ Single Use Clip Applier is intended for patients undergoing laparoscopic surgical procedures and can achieve dissection and ligation of blood vessels and other tubular structures for radiographic marking.

6. COMPARISION OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

SOLID CLIP™ Single Use Clip Applier is compared to the predicate device, Endo Clip™ II Clip Applier (K143644) and also compared to ENDO CLIP™ III 5mm Clip Applier (K121194) which is used as a reference device specifically for its size.

A side-by-side comparison conducted for clip applier performance demonstrates that SOLID CLIP™ Single Use Clip Applier is substantial equivalence to the subject device, the predicate device and the reference device. The subject device has the same intended use and similar technological characteristics with no new questions of safety or effectiveness raised. Detailed discussion is summarized in the below Comparison Charts that provide a side-by-side comparison.

Features	Subject Device	Predicate Device	Comparison
Device Name	**SOLID CLIP™ Single Use Clip Applier (K221495)**	**Endo Clip™ II Clip Applier (K143644)**	
Manufacturer	Medscope Biotech Co., Ltd.	Covidien	
Regulation Number	21 CFR 878.4300	21 CFR 878.4300	Identical
Regulation Name	Implantable clip	Implantable clip	Identical
Regulatory Class	Class II	Class II	Identical
Product Code	FZP	FZP	Identical
Indications for use	The SOLID CLIP™ Single Use Clip Applier is intended for patients undergoing endoscopic procedures and can achieve occlusion of vessels and other tubular structures , and for radiographic marking.	The Endo Clip™ II Clip Applier has application in many types of endoscopic procedures to achieve occlusion of vessels and other tubular structures, and for radiographic markings.	Identical
Contraindications	◆ The SOLID CLIP™ Single Use Clip Applier is not intended for contraceptive tubal occlusion, but may be used to achieve hemostasis following transection of the fallopian tube. ◆ Do not use the SOLID CLIP™ Single Use Clip Applier on the central circulatory system, renal artery, iliac artery, or other vessels which metal ligating clips would not normally be used.	◆ The device is not intended for contraceptive tubal occlusion, but may be used to achieve hemostasis following transection of the fallopian tube. ◆ Do not use the ENDO CLIP™ II disposable clip applier on the central circulatory system, renal artery, iliac artery, or other vessels which metal ligating clips would not normally be used.	Identical
Description	◆ Sterile ◆ Single patient use	◆ Sterile ◆ Single patient use	Identical

Features	Subject Device	Predicate Device	Comparison
	◆ Disposable	◆ Disposable	
Sterilization Process	Ethylene Oxide	Ethylene Oxide	Identical
Shelf Life	3 years	5 years	Difference. Performing the shelf-life stability test has shown not to affect safety and performance.
Technical specification			
Shaft diameter	10mm or 5mm	10mm	Similar. 5mm was compared to the reference device
Shaft length	330mm	290mm	Similar. Different design feature to transport the clips when firing the trigger
Surgical field	15°	15°	Identical
Configuration	Jaw, shaft, rotation knob, trigger, handle	Jaw, shaft, rotation collar, trigger, handle	Identical
Handle and Trigger	Pistol-grip configuration with actuation trigger	Pistol-grip configuration with actuation trigger	Identical
Shaft Rotation	360-degree rotation knob in either direction	360-degree rotation collar in either direction	Similar. Different mechanism, but the same purpose
Clip Indicator	Yellow block appears when 5 or fewer clips remain in the device	Yellow bar which appears when the applier is empty	Similar. Different mechanism, but the same purpose
Clip Material	Titanium	Titanium	Identical
Clip Size & Quantity	ML : 10, 15, 20pcs; L : 10, 15pcs	ML : 20pcs	Similar. 5mm was compared to the reference device. Large size represents a larger clip length.
Clip Open Width	4.5mm	4.5mm	Identical
Clip Closed Length	ML: 9mm; L: 11mm	ML: 9mm	Similar. Large size represents a larger clip length.
Clip Geometry	U-shape U-shape with larger back span	U-shape	Identical

Features	Subject Device	Predicate Device	Comparison
	angle allows vessels to the back of the clip during approximation.		
Last Clip Lockout	Safety interlock feature. The trigger cannot be squeezed shut when the clip is empty to prevent empty jaw closure to damage a structure or vessel.	Safety-interlock handle design	Identical
Performance			
Clip Formation	Pass	Pass	Identical
Clipped Gap	0.17 mm	0.18 mm	Similar
Clipped Step Difference	0.06 mm	0.02 mm	Similar. All meet the criteria.
Clipped Pull-out Force	314 g	258 g	Identical
Clipped Slip Force	884 g	933 g	Similar. All meet the criteria.
Airtight Capability	Pass	Pass	Identical
Trigger Initial Force	2.3 kg	1.7 kg	Similar. All meet the criteria.
Package	Blister with Tyvek lid	Blister with Tyvek lid	Identical

7. NON-CLINICAL TEST

The following non-clinical tests were provided in support of the substantial equivalence determination.

No	Test Item	Reference Standard	Results
1	Biocompatibility	ISO 10993 FDA guidance	Pass
2	Performance Study (Functional Testing)	N/A	Pass
3	Performance Study (Animal Testing)	FDA guidance	Pass
4	Sterilization and Stability Testing	ISO 11135 ISO 11737-1 ISO 11737-2 ISO 11607-1 ISO 11607-2 ASTM F1140 ASTM F1929 ASTM F88 ASTM F1608	Pass

No	Test Item	Reference Standard	Results
5	MR Compatibility Assessment	ASTM F2052 ASTM F2213 ASTM F2182 ASTM F2119	MR safety information disclosed in the labeling and IFU

8. CONCLUSIONS

The non-clinical data support SOLID CLIP™ Single Use Clip Applier with implantable titanium clip perform comparably to the predicate device and the reference device to demonstrate similar intended use and technological characteristics and can be able to achieve the same effectiveness and safety as the legally marketed predicate device (K143644).