April 15, 2024

Veol Medical Technologies Pvt Ltd.
℅ Bruno Milhoci
Regulatory Affairs Consultant
Passarini
Rua Alice Além Saadi, Av. Pres. Castelo Branco,
855 - Sala 2404
Ribeirão Preto, SP 14096-570
Brazil

Re: K240205
Trade/Device Name: Ez Catch Auto; Ez Catch YR; Ez Catch TR
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 15, 2024
Received: January 25, 2024

Dear Bruno Milhoci:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.04.15 15:10:38 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General 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

Ez Catch Auto;
Ez Catch YR;
Ez Catch TR

Indications for Use *(Describe)*

The device is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic procedures.

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

Prepared on: 2024-04-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Veol Medical Technologies Pvt Ltd.
Applicant Address	A 747, MIDC Pawane, TTC Industrial Area, Kopar Khairane, Navi Mumbai, Maharashtra 400705 Navi Mumbai Maharashtra 400705 India
Applicant Contact Telephone	+918552932249
Applicant Contact	Ms. Sneha Pandit
Applicant Contact Email	sp@veolmedtech.com
Correspondent Name	Passarini
Correspondent Address	Rua Alice Além Saadi, Av. Pres. Castelo Branco, 855 - Sala 2404 Ribeirão Preto sp 14096-570 Brazil
Correspondent Contact Telephone	+5516982160239
Correspondent Contact	Mr. Bruno Milhoci
Correspondent Contact Email	bruno@passarini.com.br

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ez Catch Auto; Ez Catch YR; Ez Catch TR
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Number	876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201243	Disposable Specimen Retrieval Bag	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

The EzCatch Tissue Retrieval Bag consists of a long cylindrical tube (Deployer Handpiece/ Introducer) and a polyurethane bag (Tissue Retrieval Bag) that minimizes spillage and intraoperative contamination by isolating and containing specimens. This device is designed for introduction and use through all appropriately sized trocar sleeve (of generally 10mm size).
The EzCatch Tissue Retrieval Bag has application for safe, convenient removal of tissue specimens such as the appendix, an ectopic pregnancy, gallbladder, gallstones, lymph nodes, ovaries, small sections of bowel and other tissue structures.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The device is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic procedures.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same

Technological Comparison

21 CFR 807.92(a)(6)

Based on the comparison table above, the subject device and the predicate device are substantially equivament.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The non-clinical tests were performed in the subject device and on predicate device. In total 6 comparative tests were performed:
- Leak Test
- Force to push out retracted bag test
- Force to withdraw retracted bag test
- Penetration force test
- Tightening Line Tensile Strength Test
- Retracted Bag Peeling Force Test

The followinf tests were conducted in the subject device:
- Sterilization validation
- EO, ECH residues
- Shelf Life testing
- Biocompatibility testing accoding to ISO10993-1

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent to the predicate devices.