October 30, 2024

Nicholas See
IDE Vision, Ltd.
Lodge Way
Portskewett
Caldicot, NP265PS
United Kingdom

Re: K240847
Trade/Device Name: MedicCO2LON (MedicCO2LON)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FCX
Dated: October 3, 2024
Received: October 3, 2024

Dear Nicholas See:

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,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*

K240847

Device Name

MedicCO2LON (MedicCO2LON)

Indications for Use *(Describe)*

The MedicCO2LON device is intended to be used for colonic distension with CO_2 gas for CT Colonography and conventional Colonoscopy procedures.

MedicCO2LON is designed to function with specific colonic insufflation administration sets that allow passage of gas from the device to the colorectal cavity. MedicCO2LON should only be used with administration sets specifically designed for this purpose.

The device should only be used by personnel trained in the practice of undertaking CT Colonography and conventional Colonoscopy examinations and the use of an automatic insufflation device.

The device should only be used for CT Colonography or conventional Colonoscopy procedures and should not be used for any other patient examination procedure.

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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510K Summary

Date prepared 9th May 2024, Updated 23rd October 2023

General Information:

Contact Person:	Nicholas Adrian See
Address:	IDE Vision Ltd Lodge Way Portskewett Caldicot NP26 5PS Monmouthshire United Kingdom
Telephone:	+(44) 1291 425425
Email:	nick@doppler.co.uk

Device Identification:

Trade Name:	MedicCO2LON (MedicCO2LON)
Common Name:	Insufflator, Colonic
Classification Name:	Endoscope and accessories 21 CFR 876.1500
Product Code:	FCX

Predicate Device Information:

Predicate Device:	BRACCO PROTOC0$_2$L TOUCH Colon Insufflator 510(k) K132192

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Device Description:

MedicCO2LON is an automated insufflation device designed for administering and regulating colonic distension by insufflation with carbon dioxide gas, in preparation for and during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.

Construction:

The MedicCO2LON colonic insufflator is constructed using a plastic (PC/ABS) external shell covering a metal internal frame, internal components are low voltage (3.3V, 12V and 24V DC) powered from an internal mains connected power supply.

None of the parts of the MedicCO2LON contact the patient directly and the user only has transient contact with the unit, with it being table or trolley mounted.

Use period:

The units are for short term use (normally no more than 30 min) and provides, to the patient, CO2 via an external pressure regulator to the device to insufflate the patient using a standard administration set at up to 30mmHg

Intended Use:

The MedicCO2LON device is intended to be used for colonic distension with CO_2 gas for CT Colonography and conventional Colonoscopy procedures.

MedicCO2LON is designed to function with specific colonic insufflation administration sets that allow passage of gas from the device to the colorectal cavity. MedicCO2LON should only be used with administration sets specifically designed for this purpose.

The device should only be used by personnel trained in the practice of undertaking CT Colonography and conventional Colonoscopy examinations and the use of an automatic insufflation device.

The device should only be used for CT Colonography or conventional Colonoscopy procedures and should not be used for any other patient examination procedure.

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Product Comparison:

Parameter	MedicCO2LON	PROTOC0$_2$L TOUCH
510(k)		K132192
Indication for Use	Administer and regulate C02 as a distention media for the colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.	Administer and regulate C02 as a distention media for the colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.
Applied Gas	CO_2	CO_2
Design	Electro-Mechanical Pneumatic System to regulate both Flow and Pressure of CO_2	Electro-Mechanical Pneumatic System to regulate both Flow and Pressure of CO_2
Anatomical Sites	Rectal administration of CO_2 via enema tip or catheter lumen	Rectal administration of CO_2 via enema tip or catheter lumen
Radiation	No ionizing radiation emitted	No ionizing radiation emitted
Thermal	No thermal energy introduced into patient.	No thermal energy introduced into patient.
Power supply	Switch Mode Power supply housed within unit	Switch Mode Power supply housed within unit
User Connections	IEC Mains inlet, Low pressure CO_2 input Controlled Gas output	IEC Mains inlet, Low pressure CO_2 input Controlled Gas output
Display type	LED Back lit colour LCD, Display Area 152 x 91mm	Back lit colour LCD,
Displayed data	Current output pressure Gas Flow Rate Delivered gas volume Gas supply level	Current output pressure Delivered gas volume Gas supply level

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Controls type	Graphic touch screen controls	Graphic touch screen controls
Controls data	Start / Stop / Resume Flow Reset Delivered Volume Set Target pressure Set Maximum Flow	Start / Stop Flow Reset Delivered Volume Set Target Pressure
Gas Control		
Maximum total gas volume	12.0 L	No maximum limit
Gas Volume Profile	Flow stops at: 4,6,8,10,12L	Flow stops at 3L to 10L
Default target flow rate	3.0 LPM	3.0LPM
Gas Flow Start Profile	0.5lpm per 0.5l delivered volume to target flow rate	1.0lpm for 0 to 0.5l delivered volume 2.0lpm for 0.5 to 1.0l delivered volume 3.0lpm for greater than 1.0l delivered volume
Target pressure	0 to 30mmhg Default 20 mmHg	0 to 35mmHg

Volume Accuracy	+/-20% of current reading display	Unknown
Flow Adjustment	0.5LPM	1.0LPM
Flow Accuracy	+/-10% at 3LPM	+20% @ 3LPM
Pressure Accuracy	+/- 1mmHg of current reading	+/- 10%
Safely overpressure Relief	Independent Redundant Mechanical Relief	Independent Redundant Mechanical Relief
Safety Pressure Relief pressure (mechanical)	1.5psi (78mmHg) nominal	75mmHg
Safety Pressure Relief Accuracy (mechanical)	+/- 20% of trip pressure	Unknown

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Safety Pressure Relief pressure (Electronic)	50mmHg for 5 seconds	50mmHg for 5 seconds

In all cases the insufflation gas is CO_2 and this is externally connected to the units which then deliver it via an external Administration Kit. The control interfaces and displays vary slightly with 1 unit using touch screen LCD and the ProtoCO_2L using an LED display and mechanical controls.

The data displayed is the same in style but the MedicCO2Lon adds a display of the delivery gas flow rate to provide the doctor with an indication as to the rate the gas is entering the patient.

Both units deliver a volume of gas of at least 12L with the MedicCO_2LON delivering 12L and the ProtoCO_2L having no limit. The normal delivered volume for insufflation is between 2 – 4L, allowing for leaks 12L will be enough for all patients. Should more gas be required it implies a serious leak and this should be investigated rather than allowing limitless gas to enter the patient.

Pressure on the MedicCO2LON has a target of 30mmHg with the ProtoCO_2L having a 25mmHg maximum. In all cases these values can be set to different levels by the doctor and the MedicCO2LON has pre-sets that can be set to any level the doctors require up to 30mmHg and these values are recalled for each patient.

The flow rate on both units is the same with a maximum of 3LPM, the MedicCO2LON allows an increase in 0.5LPM steps while the ProtoCO_2L uses 1LPM steps. The smaller the steps the less stress applied to the patient.

Both units use mechanical safety pressure discharge valves set at 75 – 78mmHg.

Conclusion:

The MedicCO2LON device for colonic distension with CO_2 gas for CT Colonography and conventional Colonoscopy procedures is considered to be substantially equivalent to the predicate device. It does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

Clinical:

The units are used for the same clinical condition and purpose.

They are used at the same site in the body;

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They all use the same Administration Kit to supply the gas into the patient.

The units have similar critical performance according to expected clinical effect its intended use.

Technical:

The MedicCO2LON and the other unit are used under similar conditions of use.

The MedicCO2LON has similar specifications and properties.

The MedicCO2LON is of similar design being a standalone mains connected insufflator supplied externally with CO_2.

The MedicCO2LON has similar principles of operation, Pressure, Flow, Volume and connection to the Patient.

Biological:

The MedicCO2LON uses the same materials in contact with the same human tissues in that the Administration Set (not manufactured my Ultrasound Technologies Ltd) is the same or similar to all others on the market. The Kits are ALL interchangeable and depend on the hospitals purchasing arrangements.

Tested Predicate Comparison.

All characteristics have been tested and are detailed in the documents listed:

A summery is as follows:

Function	**MedicCO2LON Performance**	**Test report document Identification**	**Predicate device Performance**
Displayed Data			
	Current Input Pressure	MCODOC121-102 Appendix Image	Current output pressure
	Gas Flow Rate	MCODOC121-102 Appendix Image	Not defined
	Delivered Gas Volume	MCODOC121-102 Appendix Image	Delivered Gas Volume
	Gas Supply level	MCODOC121-102 Appendix Image	Gas Supply level
Touch Screen Control Data			
	Start / Stop / Resume flow	MCODOC121-102 Appendix Image	Start / Stop flow
	Reset Delivered Volume	MCODOC121-102 Appendix Image	Reset Delivered Volume

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	Set Target Pressure	MCODOC121-102 Appendix Image	Set Target Pressure
	Set Maximum Flow	MCODOC121-102 Appendix Image	Not defined
Maximum total gas volume	12.0L	MCODOC166-101 Page 7 section 3.3	Not defined
Gas Volume Profile	Stops at 4,6,8,10,12L	MCODOC121-102 Volume Accuracy test	Stops at 3L to 10L
Default target flow rate	3.0LPM	Power up default on screen	3.0LPM
Gas Flow Start Profile	0.5LPM per 0.5L Volume.	MCODOC121-102 Flow rate Accuracy test	1.0LPM for 0 to 0.5L delivered volume. 2.0LPM for 0.5 to 1.0L delivered volume. 3.0LPM for greater than 1.0L delivered volume.
Target Pressure	0 to 30mmHg	MCODOC121-102 Pressure Accuracy test	0 to 35mmHg
Volume Accuracy	+/- 20% at current reading.	MCODOC121-102 Volume Accuracy test	Not defined
Flow Adjustment	0.5LPM	MCODOC121-102 Flow rate Accuracy test	1.0LPM
Flow Accuracy	+/- 10% at 3LPM	MCODOC121-102 Flow rate Accuracy test	+20% at 3LPM
Pressure Accuracy	+/- 1mmHg of current reading	MCODOC121-102 Pressure Accuracy test	+/-10%
Safety overpressure relief	Independent redundant mechanical relief	MCODOC166-101 Page 6 section 3.2	Independent redundant mechanical relief
Safety pressure relief (mechanical)	1.5psi (78mmHg)	MCODOC166-101 Page 6 section 3.2	75mmHg
Safety pressure relief accuracy (mechanical)	+/- 20mmHg of trip pressure	MCODOC166-101 Page 6 section 3.2	unknown
Safety pressure relief accuracy (electronic)	50mmHg for 5 seconds	MCODOC166-101 Page 6 section 3.2	50mmHg for 5 seconds