March 1, 2023

Medivators, Inc.
Disha Kabrawala
Senior Regulatory Affairs Specialist
14605 28th Ave North
Minneapolis, MN 55447

Re: K223040
Trade/Device Name: Endo SmartCap™
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: January 26, 2023
Received: January 30, 2023

Dear Disha Kabrawala:

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223040

Device Name
Endo SmartCap™

Indications for Use *(Describe)*
The Endo SmartCap™ is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic 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) – K2203040 Summary
For
Endo SmartCap™

Medivators Inc
14605 28th Ave N,
Minneapolis, MN 55447
Fax No: 844-348-5637

Contact Person: Disha Kabrawala
Senior Regulatory Affairs Specialist
Phone: 732-319-7766
Email: Disha.Kabrawala@cantel.com

Summary Date: October 19, 2022

1. Device Name

Trade Name:	Endo SmartCap™
510(K)	K2203040
Device Class:	II
Common/usual Name:	Sterile Water Bottle Adapter
Classification Name:	Endoscopes and Accessories
Classification Number:	21 CFR 876.1500
Product Code:	FAJ

2. Predicate Devices

K093665: ENDO SMARTCAP

3. Description of Devices

The Endo SmartCap™ supplies sterile water and either air or CO2 to an endoscope during endoscopic procedures when connected to a sterile water source and an air or CO2 source. Two tubes are arranged coaxially; air or CO2 supplied through the outer tube pressurizes the sterile water container, forcing water up through the inner tube and to the endoscope. The proximal end of the tube set includes a bottle cap for attachment to a user-provided sterile water container; the Endo SmartCap™ is compatible with all major brands of sterile water containers. The proximal end of the tube set terminates in a tube weight which keeps the tip of the tubing submerged. A pinch clip prevents water from dripping from the tube's distal end when the device is detached from the endoscope. The distal end of the tube set terminates in a connector which mates with the corresponding brand of endoscope; Endo SmartCap™ models are available for all major brands of endoscopes. The device is provided sterile (EtO). The device is fabricated from metals, plastics, and elastomers. The Endo SmartCap™ is intended for 24 hour multi-patient use and should be discarded daily. No portion of the device comes in direct contact with patients.

4. Intended Use / Indications for Use

The Endo SmartCap™ is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic procedures.

5. Comparison of Technological Characteristics with the Predicate Device

The Endo SmartCap™ is the same as the predicate device with the exception of the proposed modification. A comparison between the proposed and predicate devices is included in **Table 1**. Since there are no technological differences between the proposed and predicate devices, there are no new concerns of safety and effectiveness.

Table 1.: Physical Description and Technological Properties vs the Predicate Device

Feature	Proposed Endo SmartCap	Predicate (K093665) Endo SmartCap	Comparison
Indications for Use	The Endo SmartCap™ is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic procedures.	The Endo SmartCap™ is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic procedures.	Identical

Feature	Proposed Endo SmartCap	Predicate (K093665) Endo SmartCap	Comparison
Device Use/Principle of operation	The Endo SmartCap tubesets' mode of operation is the same as the device provided by the endoscope manufacturer when installed to commonly used sterile water bottles used in endoscopic procedures. The threaded cap is installed onto commonly used, readily available sterile water bottles and uses a coaxial tube to partition water and air/CO2 which is connected to the endoscope-interfacing connector. Pressurized air or CO2 provided by the endoscope's processor/light source or a CO2 insufflator is fed into the endoscope (either directly or first through the Endo SmartCap & bottle system via luer connection).	The Endo SmartCap tubesets' mode of operation is the same as the device provided by the endoscope manufacturer when installed to commonly used sterile water bottles used in endoscopic procedures. The threaded cap is installed onto commonly used, readily available sterile water bottles and uses a coaxial tube to partition water and air/CO2 which is connected to the endoscope-interfacing connector. Pressurized air or CO2 provided by the endoscope's processor/light source or a CO2 insufflator is fed into the endoscope (either directly or first through the Endo SmartCap & bottle system via luer connection).	Identical
Intended Use	Daily (24hr) multi-patient use	Daily (24hr) multi-patient use	Identical
Reprocessing	None; Daily disposal	None; Daily disposal	Identical
Patient Contact	No direct contact	No direct contact	Identical
Water Bottles	Supplied by user; Disposed of daily	Supplied by user; Disposed of daily	Identical
Materials	Metals, plastics, and elastomers	Metals, plastics, and elastomers	Identical
Water Flow Rate Performance	Meet or exceed the endoscope manufacturer's requirements in the average of total volume of water flowed through the endoscopes	Meet or exceed the endoscope manufacturer's requirements in the average of total volume of water flowed through the endoscopes	Identical
Gas Flow Rate performance	Meet or exceed the endoscope manufacturer's requirements in the average of total volume of gas flowed through the endoscopes	Meet or exceed the endoscope manufacturer's requirements in the average of total volume of gas flowed through the endoscopes	Identical

6. Summary of Changes

The changes that are the subject of this submission are as follows:

- The use of Endo SmartCap source tubing, PN 100551 with the CO2Compact (K111648) and Co2Co-efficient (K053008) insufflators. There is no impact on device design. The change has been initiated to accommodate with customer need.

- The use of the Endo SmartCap CO2 source tubing, PN 100551 with Endo SmartCap- CO2 extension tubing as tubing kits. The change has been initiated to accommodate with customer preferences. There is no impact to the device design, safety and efficacy.

7. Summary of the Performance Data

The subject Endo SmartCap is equivalent to the predicate Endo SmartCap, aside from the modifications subject of this submission.

The flowrate testing and backflow prevention testing were conducted using the same methodology as that indicated in the predicate 510(k), K093665, to confirm the safety and effectiveness of the subject device has not been compromised with the device modification.

The following testing has been conducted to demonstrate that the use of a Endo SmartCap is safe and effective for its intended use:

Test	Acceptance Criteria	Result
Confirmation of flow rate	The average mean flow of the 100551-production sample must be no lower than 10% of the flow of the same tubeset without a filter	PASS
Prevention of backflow	The 100551 shall not allow water to backflow into the CO2EFFICIENT insufflator	PASS

7. Conclusion

Based on the intended use, technological characteristics and for the non-clinical performance data, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device (K093665), Class II (21 CFR 876.1500), product code FAJ.