January 19, 2018

GCE Medical Corporation
% Stephen M. Page
President
MedReg Associates Inc.
228 Hull Cove Farm Road
Jamestown, Rhode Island 02835

Re: K171673
Trade/Device Name: Focus Cap
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: January 10, 2018
Received: January 16, 2018

Dear Stephen M. Page:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K171673

Device Name
Focus Cap

Indications for Use *(Describe)*
The Focus Cap has been designed to be attached to the distal end of a colonoscope. The Focus Cap is intended for the following:

* For use in keeping the suitable depth of the colonoscope's field of view.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K171653

510(k) Summary

Submitter Information

A. *Company Name*: GCE Medical Corporation
B. *Company Address*: 2723 West Tenaya, Fresno CA 93711
C. *Company Phone*: 559-439-5757
D. *Contact Person*: Dr. Stanley Chang
E. *Summary Prepared on*: January 10, 2018

Device Identification

A. *Device Trade Name*: Focus Cap
B. *Device Common Name*: Transparent Cap
C. *Classification Name:* Endoscope and accessories
D. *Classification Number*: 21 CFR Part 876.1500
D. *Product Code*: FDF
E. *Device Class*: II

Identification of Predicate Device

Trade Name	Manufacturer	510(k)
Distal Distal Attachment	Olympus	K984358

Indications for Use

The GCE Medical Focus Cap has been designed to be attached to the distal end of a colonoscope. The Focus Cap is intended for the following:

- For use in keeping the suitable depth of the colonoscope's field of view.

Device Description

The GCE Focus Cap has the shape of a short transparent tube which is attached to the distal end of the colonoscope. The Focus Cap is designed to facilitate the scope's view during colonoscopy procedures.

The Focus Cap will be offered in two sizes:

- 11mm (Catalog #11 FC 1701)
- 13.5mm (Catalog #13 FC 1702)

The 11mm Focus Cap will fit 11.6mm and 12.8mm scopes. The 13.5mm Focus Cap will fit 13.2mm and 13.9mm scopes.

Comparison to Predicate Device:

Characteristic	Comparison to Predicate Olympus Distal Attachment (K984358)	Differences
Intended Use	Identical	N/A
Indications for Use	Identical	N/A
Fundamental scientific technology	Identical	N/A
Operating principles	Similar	The operating principle for both devices is that they attach to a scope by compression. Although there are slight differences in their relative adhesion strengths, those differences are minimal and have no impact on safety or effectivenss.
Mechanism of action	Similar	Both the predicate and proposed devices act as simple spacers. They establish a space between the end of the scope and patient's anatomy, thereby preventing the camera image from being blocked. Although the two devices have slightly different dimensional characteristics, those differences are minimal and have no impact on safety or effectiveness.
Technological aspects	Similar	The Olympus Distal Attachment incorporates a side hole which is not present on the Focus Cap. In addition, the Focus Cap incorporates a slant design while the Olympus design is flat. The slant design of the Focus

		Cap, which essentially takes the place of the side hole, allows for a wide open surface for the exit of fluid which is many times larger than the side hole on the predicate device. Therefore, these differences have no impact on safety or effectiveness.

Performance Testing

Performance testing has been completed for the GCE Focus Cap to demonstrate substantial equivalence to the predicate Olympus Distal Attachment (K984358). The Focus Cap has been subjected to the following verification and validation testing: Mechanical and biocompatibility. All test requirements were met as specified by test protocols and pre-determined acceptance criteria.

Conclusions

The subject Focus Cap and predicate Olympus Distal Attachment (K984358) share the same intended use and indications for use. Furthermore, the subject and predicate devices share the same fundamental technology and key device characteristics. Differences in design and technological characteristics between the subject and predicate devices do not raise any new questions of safety and effectiveness. The results of verification and validation support the safety and effectiveness of the Focus Cap for its intended use and provide reasonable assurance of the substantial equivalence of the subject device to the predicate Olympus Distal Attachment (K984358).