DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 23, 2017

Carbon Medical Technologies, Inc.
Andrew Adams
Director-Regulatory Affairs & Quality Assurance
1290 Hammond Road
Saint Paul, MN 55110-5867

Re: K172227
Trade/Device Name: Endoscopic Injection Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: July 24, 2017
Received: July 25, 2017

Dear Andrew Adams:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172227

Device Name
Endoscopic Injection Needle

Indications for Use *(Describe)*
The Endoscopic Injection Needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissue during an endoscopic 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Endoscopic Injection Needle

510(k) Summary

Submitter's Name, Address and Date of Submission

Andrew Adams
Director, Regulatory Affairs and Quality Assurance
Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, MN 55110

Phone: 651-653-8512
Fax: 651-407-1975

Submitted: July 20, 2017

Device Name

Trade Name:	Endoscopic Injection Needle
Common Name:	Endoscopic Injection Needle, Gastroenterology-Urology
Classification Name:	Endoscope and Accessories (21 CFR 876.1500, FBK)

Predicate Device

Carbon Medical Technologies Endoscopic Injection Needle (K042615)

Indication for Use

The Endoscopic Injection Needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissue during an endoscopic procedure.

Device Description

The Endoscopic Injection Needle consists of a luer lock hub, flexible cannula and retractable stainless steel needle at the distal tip. The hub is designed to accommodate a standard syringe. The device is supplied sterile and is for single patient use.

Technological Characteristics and Performance

The technological characteristics are equivalent to the predicate device. A Failure Modes and Effects Analysis (FMEA) was performed in order to assess the risks associated with the modifications introduced. Sterilization adoption validation and EO residual, distribution simulation, shelf life, and functional testing, along with a biocompatibility and sterile barrier packaging evaluation, confirmed that the modified device, Endoscopic Injection Needle, was substantially equivalent to the predicate device.