510(k) SUMMARY

NOV - 5 2004

K042615

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General Information

Date Prepared	September 22, 2004
Classification	Class II
Trade Name	Carbon Medical Technologies Endoscopic Injection Needle
Common Name	Endoscopic Needle
Submitter	Carbon Medical Technologies, Inc. 1290 Hammond Road St. Paul, MN 55110 651-653-8512
Contact	Robert W. Johnson Vice President of Regulatory Affairs and Quality Assurance
Predicate Device	Scerotherapy Needle Medi-Glove (K955558) CMT Endoscopic Injection Needle Carbon Medical Technologies, Inc. (K982890)

Device Description

The Carbon Medical Technologies Endoscopic Injection Needle consists of a stainless steel needle attached to a plastic insertion tube. The needle length and gauge will be identified on the label. The luer lock hub, which is molded onto the proximal end of the device, is designed to accommodate a standard syringe.

The CMT Endoscopic Injection Needle is intended for use as an accessory for currently marketed endoscopes and provides delivery of injectable materials during an endoscopic procedure. The type of material to be injected is dependent on the nature of the procedure, but may include delivery of injectable bulking agent during endoscopic procedures, sclerosing agents during esophagoscopic and gastroscopic procedures, local anesthetics during cystoscopic or laryngoscopic procedures, or saline or contrast media during colonoscopic procedures.

The CMT Endoscopic Injection Needle is provided sterile and is intended for single use only.

Indication

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

Technological Characteristics

The CMT Injection Needle consists of a stainless steel needle attached to a plastic cannula. A plastic luer lock hub is molded onto the proximal end where a standard syringe can be attached for injection of materials through the lumen of the needle into tissue. Multiple needle lengths are available to accommodate the length of the endoscope channel.

Summary

In summary, CMT believes the above listed predicate devices and the CMT Needle are substantially equivalent based on design, materials, methods of fabrication and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

Mr. Robert W. Johnson
Vice President, Regulatory and Clinical Affairs
and Quality Assurance
Carbon Medical Technologies, Inc.
1290 Hammond Road
ST PAUL MN 55110-5867

Re: K042615
Trade/Device Name: Carbon Medical Technologies Endoscopic Injection Needle
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FBK
Dated: September 22, 2004
Received: September 24, 2004

Dear Mr. Johnson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042615

Device Name: Carbon Medical Technologies Endoscopic Injection Needle

Indications For Use:

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

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042615