APR 3 0 2003

K030451

510(k) Summary

Submitter's Name, Address, and Date of Submission

Robert W. Johnson
Vice President of Regulatory, Clinical and Quality Assurance
Carbon Medical Technologies, Inc.
1290 Hammond Road
St. Paul, MN 55110
Phone: 651-762-2146
Fax: 651-407-1975

Submitted: February 7, 2003

Device Name

Trade Name:	Carbon Medical Technologies Injection Needle
Classification:	Class II
Classification Name:	Endoscope and/or Accessories, 21 CFR 876.1500
Common/Usual Name:	Endoscopic Injection Needles
Predicate Device:	Advanced UroScience, Inc. Injection Needle [(K)002323] Ocean Medical Products Single Wall Introducer Needle [(K)843719]

Intended Use

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

Device Description

The Carbon Medical Injection Needle consists of a stainless steel needle attached to two or more luer lock hubs. A standard syringe can be attached to the hubs for injection of materials through the lumen of the needle into tissue. Multiple needle lengths and gauges are available.

Technological Characteristics and Performance

The technological characteristics are substantially equivalent to the predicate devices. Biocompatibility and bench testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2003

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: K030451
Trade/Device Name: Carbon Medical Technologies Injection Needle
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FBK
Dated: February 7, 2003
Received: February 11, 2003

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 (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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Statement

K030451

510(k) Number (if known) K030451

Device Name Carbon Medical Technologies 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 tissues during endoscopic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

David A. Seguran

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030451

(Optimal Format 1-2-96)