MAY 1 3 2014

5. 510(k) Summary

Andrew Adams
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Submitted: September 27, 2013

Device Name

Trade Name:	BiomarC Coaxial Needle
Classification Name:	Endoscopic Injection Needle, 21 CFR 876.1500, FBK Implantable Clip, 21 CFR 878.4300, NEU
Common/Usual Name:	Coaxial Needle

Predicate Devices

Carbon Medical Technologies Endoscopic Injection Needle (K042615),
by Carbon Medical Technologies, Inc.
Coaxial Biopsy Needle (K936194),
by Bard Gynecology & Radiology

Indication for Use

The BiomarC Coaxial Needle allows delivery of fiducial markers into soft tissue.

Device Description

The BiomarC Coaxial Needle is a sterile, pyrogen free, single patient use, disposable coaxial needle that consists of an outer cannula with an attached female luer lock hub, an inner stylet with an attached male luer lock hub, and a flexible slip ring style depth stop.

The BiomarC Coaxial Needle is designed for use with BiomarC Fiducial Markers. The outer cannula is only one gauge size larger than the appropriate BiomarC Fiducial Marker needle, e.g., 18g BiomarC Coaxial Needle for a 19g BiomarC Fiducial Marker needle.

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Technological Characteristics and Performance

The technological characteristics and performance of the BiomarC Coaxial Needle are substantially equivalent to the predicate devices (Table 5).

Characteristic	Proposed Device	Predicate Device	Predicate Device
Trade name	BiomarC Coaxial Needle	Carbon Medical Technologies Endoscopic Injection Needle	Coaxial Biopsy Needle
510(k) number		K042615	K936194
510(k) holder	Carbon Medical Technologies, Inc.	Carbon Medical Technologies, Inc.	Bard Gynecology and Radiology
Indications for use	The BiomarC Coaxial Needle allows delivery of fiducial markers into soft tissue.	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.	The coaxial biopsy needle guide is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, spleen, lymph nodes and various soft tissue lesions.
Use	Single use	Single use	Single use
Sterility	Sterilized by EO with an SAL of $1x10^{-6}$	Sterilized by EO with an SAL of $1x10^{-6}$	Sterilized by EO
Pyrogens	Pyrogen free	Pyrogen free	Pyrogen free
Cannula/stylet rod material	Stainless steel, type 304	Stainless steel	Stainless steel
Tip style	Trocar tip	Spinal tip	Trocar or blunt tip
Device body contact category	External communicating device, tissue, limited	External communicating device, tissue, limited	External communicating device, tissue, limited
Safety	Safety has been established for the identical nature and duration of patient contact through a history of use in other similar devices.	Safety has been established for the identical nature and duration of patient contact through a history of use in other identical and similar devices.	Unknown
Performance	Able to create a channel through soft tissue	Able to create a channel through soft tissue	Able to create a channel through soft tissue
	Able to allow delivery of fiducial markers through channel created	Able to allow delivery of injectable materials through channel created	Able to guide another device through channel created

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

May 13, 2014

Carbon Medical Technologies Incorporated
Mr. Andrew J. Adams
Director, Regulatory Affairs & Quality Assurance
1290 Hammond Road
Saint Paul, Minnesota 55110

Re: K133148
Trade/Device Name: BiomarC Coaxial Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK, NEU
Dated: March 6, 2014
Received: March 7, 2014

Dear Mr. 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 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" (21CFR 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 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 yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number: K133148

Device Name: BiomarC Coaxial Needle

Indications for Use:

The BiomarC Coaxial Needle allows delivery of fiducial markers into soft tissue.

Prescription Use __X__ 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)

Joshua C. Nipper -S