AUG 21 2003

ATTACHMENT 4

510(K) SUMMARY K032347 (p.1 of 2)

Submitter's Name, Address and Date of Submission

Robert W. Johnson
Vice President, 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 28, 2003

Device Name

Trade Name: BiomarC® Tissue Marker

Classification Name: Implantable Staple, 21 CFR 878.4750

Common/Usual Name: Tissue Marker

Predicate Device

BiomarC Tissue Marker (K001807)

Indication for Use

BiomarC Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Device Description

BiomarC is a sterile, nonpyrogenic, single use tissue marker consisting of a non-absorbable pyrolytic carbon coated zirconium oxide marker that is clearly visible on standard radiographs as well as Magnetic Resonance Imaging (MRI) and ultrasound. BiomarC is provided alone or with the BiomarC Delivery Gel. BiomarC is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a location.

Technological Characteristics and Performance

The technological characteristics are equivalent to the predicate device. 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

AUG 21 2003

Mr. Robert W. Johnson
Vice President, Regulatory Affairs
and Quality Assurance
Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, Minnesota 55110

Re: K032347
Trade/Device Name: BiomarC Tissue Marker
Regulation Number: 21 CFR 878.4750, 878.4300
Regulation Name: Implantable staple, implantable clip
Regulatory Class: II
Product Code: GDW, NEU
Dated: July 28, 2003
Received: July 30, 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 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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 2

Indications for Use Statement

510(k) Number (if known) K032347

Device Name **BiomarC Tissue Marker**

Indications for Use

The BiomarC Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032347