510(k) Summary of Safety and Effectiveness

K032217 (P.1 of 2)

Date Prepared: July 18, 2003

Submitted by:

Artemis Medical, Inc.
21021 Corsair Blvd., Suite 100
Hayward, CA 94545
Contact: Allan L. Abati, Ph.D.
VP Regulatory/Clinical Affairs and QA
Phone: (510) 259-3150
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Trade Name: 14G CORMARK™ Biopsy Site Identifier

Common Name: Tissue Marker

Classification Name: Implantable Clip or Staple
21CFR 878.4300
21CFR 878.4750

Predicate Device: Caris™ Site Marker

Intended Use:

The 14G CORMARK™ Biopsy Site Identifier is intended for use during an open surgical or percutaneous breast biopsy procedure to mark the biopsy site.

Device Description

The 14G CORMARK™ Biopsy Site Identifier is composed of a bioresorbable collagen plug embedded with a titanium non-resorbable radiopaque marker or clip.

At the completion of a breast biopsy procedure, the marker is deployed into the biopsy cavity, using a stainless steel syringe-like applicator with 1 cm markings to aid in needle placement. The marker is intended to help relocate the biopsy site for any subsequent intervention or diagnosis. The collagen slowly absorbs and the titanium radiopaque marker is left behind as the permanent identifier of the biopsy site.

Technological Characteristics

The Artemis 14G CORMARK™ Biopsy Site Identifier has the same intended use, principles of operation, materials, and technological characteristics as the Artemis Caris™ Site Marker. Each of these devices is intended for use during an open surgical or percutaneous breast biopsy procedure to mark the biopsy site. Both devices consist of two portions: a bioresorbable collagen plug embedded with a radiopaque titanium permanent marker, and a syringe-like delivery system that can be directed to the biopsy site by the

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user or inserted through an appropriate percutaneous coaxial introducer for placement of the site marker in the desired location.

The only modifications from the predicate device are: a) a change from a Pebax syringe-like applicator to a stainless steel syringe-like applicator with etched cm markings, and b) a change in the dimensions of the syringe-like applicator, collagen plug and titanium wire to accommodate 14G core needle biopsy procedures, which by design produce smaller biopsy cavities.

Risk analysis activities relevant to the design modifications included a Hazard Analysis, a Failure Mode Effects Analysis and tests related to the design modifications. The device passed all design verification and validation tests conducted.

Summary

In summary, the 14G CORMARK™ Biopsy Site Identifier has the same indications for use, and is similar in design, materials, technological characteristics, and functionality as the predicate device. The modifications are minor and do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Allan L. Abati, Ph.D.
Vice President Regulatory/Clinical Affairs
and Quality Assurance
Artemis Medical, Inc.
21021 Corsair Boulevard, Suite 100
Hayward, California 94545

Re: K032217
Trade/Device Name: 14G corMARK™ Biopsy Site Identifier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP, NEU
Dated: July 18, 2003
Received: July 28, 2003

Dear Dr. Abati:

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.

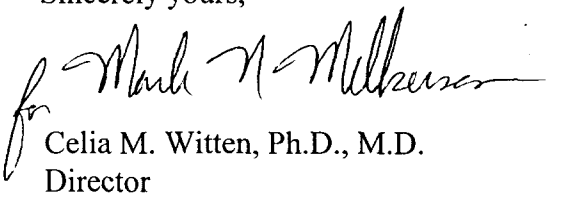
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

INDICATION FOR USE STATEMENT

510(k) Number: K032217

Device Name:

14G CORMARK™ Biopsy Site Identifier

Indication for Use:

The 14G CORMARK™ Biopsy Site Identifier is intended for use during an open surgical or percutaneous breast biopsy procedure to mark the biopsy site.

(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)

(Optional Format 1-2-96)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K03 2217