K991486

Summary of Safety and Effectiveness for the Endomyocardial Cardiac Biopsy Forceps

NOV - 5 1999

Submitted by

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Identification of a Legally Marketed Predicate Device

The Medcanica, Inc. Endomyocardial Biopsy Forceps (EMB) is substantially equivalent to the BiPal Biopsy Forceps manufactured and marketed by the Cordis Corporation pursuant to 510(k) K914567.

General Description

The EMB is sterile, single use, radiopaque, disposable device that is delivered non-toxic and non-pyrogenic. The device is transvascularly deployed to the right ventricle of the heart for the acquisition of endomyocardial tissue samples Typically, the approach is made from the jugular vein or femoral arteries.

The EMB consists of 4 major components: the moveable handle, end-effectors (jaws), core wire, and sheath. The core wire is attached to the handle. Moving the handle opens and closes the jaws. A typical EMB is shown in Figure 1, EMB (Jaws Open). Details of the jaws are shown separately in Figure 2, Jaw Assembly.

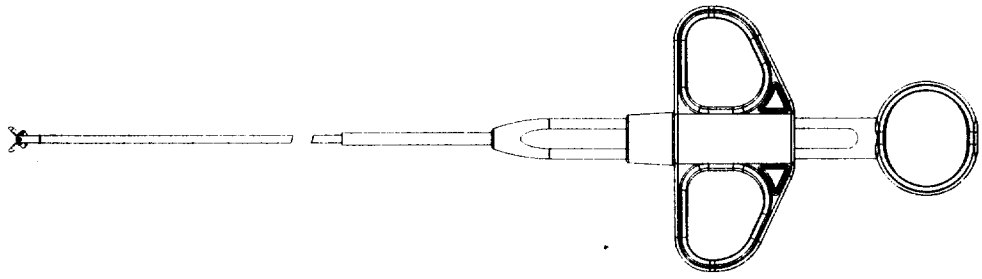

Figure 1, EMB (Jaws Open)

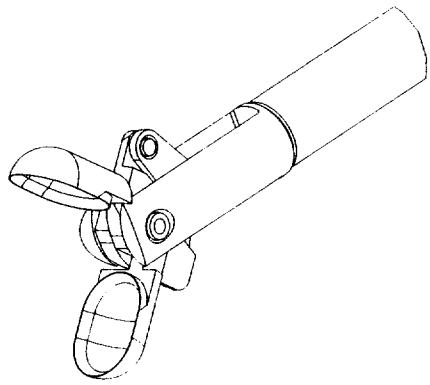

Figure 2, Jaw Assembly

Intended Use

The Endomyocardial Biopsy Forceps are designed for endomyocardial biopsies.

Summary of Technological Characteristics

The table below compares the technological characteristics of the EMB to the predicate device.

Feature	EMB	Predicate Device
510(k) Number	To be determined	K914567
Manufacturer	Medcanica, Inc.	Cordis Corporation
Sterile packaging	Mylar®/Tyvek® Pouch, Box	Mylar®/Tyvek® Pouch, Box
Sterilization method	Ethylene Oxide	Ethylene Oxide
Single Use	Yes	Yes
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Shelf life	1 year initially, 3 years subsequent to accelerated aging tests	3 years
Intended use	The Endomyocardial Biopsy Forceps are designed for endomyocardial biopsies.	The Cordis biopsy forceps are designed for endomyocardial biopsies.
Formable tip	Yes	Yes
Radiopaque	Yes	Yes
Available Sizes	5.4 and 7.0 French	5.4 and 7.0 French
Working lengths (cm)	50 and 105	50 and 104
Jaw action	Double-action (both jaws move)	Double-action (both jaws move)

Feature	EMB	Predicate Device
Tip curve orientation marker	Handle Logo	Handle Logo
Recirculating Blood Contact outer sheath	Teflon®, (FEP)	Teflon®, (PTFE)
Recirculating Blood Contact Metallic Parts	Stainless Steel	Stainless Steel
Color Coding	Yes	Yes
Jaw Size Indication	Handle Logo	Strain Relief Logo
Handle	3-ring pull type	3-ring pull type
F5.4 minimum recommended sheath size (French)	6	6
F7.0 recommended sheath size (French)	7	7
Calculated (Labeled) Jaw Volume 5.4 F (mm^3)	2.20	1.84
Calculated (Labeled) Jaw Volume 7.0 F (mm^3)	5.20	5.03

Summary of Performance Data

The EMB meets the requirements of the following recognized consensus standards.

- ASTM F899 – 95, Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments
- Biological Evaluation of Medical Devices—Part 7: Ethylene oxide sterilization residuals, American National Standard, ANSI/AAMI/ISO 10993-7:1995
- Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization, ANSI/AAMI/ISO 11135-1994, Approved March 24, 1994 by the American National Standards Institute, Inc.

Additionally, the EMB complies with the following standards:

- Ethylene Oxide, Ethylene Chlorhydrin, and Ethylene Glycol, Proposed Maximum Residue Limits and Maximum Levels of Exposure, 21 CFR, § 821.100, Proposed Rule, June 23, 1978.

The EMB is substantially equivalent to the cardiac biopsy forceps manufactured and marketed by the Cordis Corporation pursuant to 510(k) K914567. Extensive bench testing of

both devices has demonstrated this. Testing includes tensile, flexibility, dimensional, and performance tests. Furthermore, the device has similar technological characteristics to Cordis cardiac biopsy forceps.

The recirculating blood contact materials of the device have been carefully selected for their long history of biocompatibility.

Since the EMB meets the requirements of the stated standards and embodies technological characteristics essentially identical to those of the predicate device, we believe the device is safe and effective and that it performs as well as or better than the predicate device. The device has been designed and developed utilizing design control methods in compliance with the GMP. The EMB will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 5 1999

Mr. Matthew A. Palmer
President
Medcanica, Inc.
19526 E. Lake Drive
Miami, FL 33015

Re: K991486
ULTRA-CBX
Regulatory Class: II (Two)
Product Code: DWZ
Dated: August 6, 1999
Received: August 9, 1999

Dear Mr. Palmer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 for

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

Enclosure

Indications for Use

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510(k) Number (if known): K991486

Device Name Endomyocardial Biopsy Forceps

Indications for Use:

—The Endomyocardial Biopsy Forceps are designed for endomyocardial biopsies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991486

Prescription Use X OR Over-The-Counter Use Nc
(Per 21 CFR 801.109)

(Optional Format 1-2-96)