
510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: August 18, 2003

510(k) number: K032584

Applicant Information:

Rubicor Medical, Inc.
849 Veterans Blvd.
Redwood City, CA 94063

Contact Person: Ary Chernomorsky
Phone Number: (650) 556-1070
Fax Number: (650) 556-1821

Device Information:

Classification: Class II
Trade Name: Rubicor EnCapsule™ Breast Biopsy Device
Classification Name: Electrosurgical Device and accessories (21 CFR 870.4400)

Equivalent Device:

The subject device and accessory are substantially equivalent in intended use and/or method of operation to the Rubicor EnCapsule™ Breast Biopsy Device (K023601 & K030049)

Intended Use:

The EnCapsule™ Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

The EnCapsule Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Test Results:*Performance*

Results of in-vitro testing demonstrate that the Rubicor EnCapsule™ Breast Biopsy Device is safe and effective for its intended function.

Summary:

Based on the intended use, product, and performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed and unmodified predicate device.



SEP 17 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rubicor Medical, Inc
c/o Robert J. Chin, Ph.D.
Regulatory Consultant
25 Hartford Avenue
San Carlos, California 94070

Re: K032584
Trade/Device Name: Rubicor EnCapsule™ Breast Biopsy Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 18, 2003
Received: August 22, 2003

Dear Dr. Chin:

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.

Page 2 - Robert J. Chin, Ph.D.

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,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

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 (if known): K032584

Device Name: Rubicor EnCapsule™ Breast Biopsy Device

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark H. Melkerson
(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K032584

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the Counter Use