K081179

510(k) Summary

Summary of Safety and Effectiveness for MammoSite® Cavity Evaluation Device

MAY - 9 2008

1. **Submitter Information:**

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Prepared: March 10, 2008

2. **Device Name:**

Proprietary Name:	MammoSite Cavity Evaluation Device
Common Name:	Cavity Evaluation Device
Classification Name:	Remote controlled radionuclide applicator system
Classification Regulation:	21 CFR 892.5700, Product Code JAQ
Device Classification:	Class II

3. **Predicate Device:**

The MammoSite Radiation Therapy System (RTS) (K011690 and K030558) has been selected as the predicate device for the MammoSite Cavity Evaluation Device (CED).

4. **Device Description:**

The MammoSite CED is used to assess the lumpectomy cavity and aid in the selection of the appropriate MammoSite RTS applicator for delivery of intracavitary radiation. It may be used during surgery to assess skin spacing and conformance, but it is not intended to deliver radiation therapy. It may be left in the lumpectomy cavity as a placeholder for up to 29 days until it is exchanged for the MammoSite RTS applicator.

The CED consists of a single-lumen silicone shaft, approximately six and one half inches long, with an inflatable silicone balloon bonded to the distal end of the catheter shaft. A rounded silicone tip caps the distal end of the catheter. A female luer and valve are connected to the proximal end of the catheter shaft. The

silicone shaft has an outer diameter of 0.214" and a durometer of 65 Shore A. The MammoSite CED is available in a spherical 4-5 cm. balloon size.

5. **Intended Use:**

The MammoSite Cavity Evaluation Device (CED) is a balloon catheter intended to be placed in the lumpectomy cavity and inflated with sterile saline or contrast solution for the purposes of:

- assessing the size and shape of the lumpectomy cavity in order to choose the appropriate MammoSite RTS applicator
- assessing skin spacing (between outer skin surface and balloon surface)
- assessing cavity conformance (fit between cavity walls and balloon surface)
- maintaining the size and shape of the cavity (acting as a placeholder) until it is exchanged for a MammoSite RTS applicator

Similar to the MammoSite RTS applicator, the CED is intended to assess skin spacing and cavity conformance; however, it differs from the MammoSite RTS applicator in that it is not intended to deliver radiation therapy and therefore has no therapeutic effect.

6. **Technical Characteristic Comparison to Predicate Devices:**

The MammoSite CED is similar in materials and construction to other MammoSite RTS applicators, utilizing the same silicone balloon and similar shaft materials. The CED can be considered a 'simplified' version of the MammoSite RTS applicator in that it does not contain an inner lumen in the shaft (through which the radiation source is inserted in the MammoSite RTS applicator) or the associated bifurcation on the proximal end (needed to allow for both a radiation port and needle-free injection port).

7. **Non-clinical performance data**

The bench testing performed for the CED was intended to address design differences with respect to its predicate. Testing that pertains to design aspects that have remained unchanged will reference MammoSite 4-5cm RTS applicator (silicone) 510(k) filing K011690.

The sterilized CED catheters and components were tested after gamma sterilization at 25-40kGy exposure. The catheters were visually inspected for rough edges, appropriate printed shaft markings, and ink adherence after wiped with alcohol and saline.

The inflated dimensions of the CED catheters were measured at several inflation cycles. The anticipated number of inflation/deflation cycles in a standard clinical procedure is three. The first is used by the physician to assess any leaks or asymmetry as specified in the IFU. The second cycle may be used by the

physician to position the inflated balloon in the cavity prior to closing the surgical site. The balloon could then be inflated to a third cycle for an evaluation of the cavity or to become a placeholder for the MammoSite RTS. The samples in the verification were tested to 8 cycles which represent a safety factor of 1.6.

Balloon dimensional consistency was evaluated by measuring the inflated balloon dimensions at the first, fourth and eighth cycle.

Balloon assembly integrity, including the strength of the bonds and the strength of the balloon material, was assessed after the eighth cycle by inflating it to failure with water. After the samples burst, the strength of the joint between the shaft and the barb adapter was tested to failure separately with a tensile test.

In combination with the results from the design verification performed for the predicate device, the tests performed for the CED demonstrate that the device meets or exceeds its performance specification and therefore performs as well or better than its predicate device.

8. Clinical performance data

No clinical performance data was collected in support of this premarket notification.

9. Conclusion

The data presented in this premarket notification provides evidence of substantial equivalence of the MammoSite CED to the chosen predicate devices, the MammoSite RTS applicators, for assessing skin spacing and conformance of the lumpectomy cavity prior to delivery of intracavitary radiation treatment using the MammoSite RTS. In addition, the CED may be used as a placeholder in the lumpectomy cavity for up to 29 days until it is replaced with the MammoSite RTS applicator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAY - 9 2008

Hologic, Inc.
% Mr. Casey Conry
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Underwriters Laboratories, Inc.
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MELVILLE NY 11747

Re: K081179
Trade/Device Name: MammoSite® Cavity Evaluation Device
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 23, 2008
Received: April 25, 2008

Dear Mr. Conry:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K081179

Device Name: MammoSite® Cavity Evaluation Device

Indications for Use:

The MammoSite Cavity Evaluation Device (CED) may be used to assess the lumpectomy cavity and aid in the selection of the appropriate MammoSite Radiation Therapy System (RTS) applicator. It may be used during surgery to assess skin spacing and conformance. The CED may also be left in the lumpectomy cavity as a placeholder until it is exchanged for the MammoSite RTS applicator.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081179