

## **Consumer Information on: MarginProbe System - P110014**

U.S. Food & Drug Administration



*This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.*

**Product Name:** MarginProbe System

**PMA Applicant:** Dune Medical Devices, Inc.

**Address:** 111 Speen St, Suite 101  
Framingham, MA 01701

**Approval Date:** December 27, 2012

**Approval Letter:** [http://www.accessdata.fda.gov/cdrh\\_docs/pdf11/p110014a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110014a.pdf)  
[1]

**What is it?** The MarginProbe System is a [diagnostic](#) [2] tool that uses electromagnetic waves. It is used by surgeons on patients undergoing surgery to remove a tumor from the breast (lumpectomy) that was diagnosed as breast cancer. The MarginProbe helps identify cancerous (malignant) tissue in the surrounding tissue (margins) of the tumor.

**How does it work?** The MarginProbe includes a console and a probe. The surgeon uses the probe to examine the surface of the removed tumor and it does not come in contact with the patient. The probe is used to help determine if the margins of the tissue are cancerous or normal (non-cancerous). The console analyzes the measurements taken by the probe and displays the readings taken by the probe to the surgeon.

**When is it used?** The MarginProbe is used during surgery on the removed tissue along with other standard methods such as imaging and palpation of the tumor.

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**What will it accomplish?** The MarginProbe helps surgeons decide if all the cancer tissue has been removed during a lumpectomy.

**When should it not be used?** The MarginProbe should not be used:

- To replace standard tissue [histopathology](#) [3] assessment.
- On removed tissue that have been exposed to saline, ultrasound gel, or local anesthetic solutions.
- Within the lumpectomy cavity.
- On tissues other than breast tissue (that is, it should not be used on Sentinel Lymph Nodes).
- Closer than 1.5 mm to a fine needle localization guidewire.

**Additional information:** The [Summary of Safety and Effectiveness Data and labeling](#) [4] are available online.

### Other Resources:

- [NIH - MedlinePlus - Breast Cancer](#) [5]

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<http://www.mdtmag.com/news/2013/01/consumer-information-marginprobe-system-p110014>

### Links:

[1] [http://www.accessdata.fda.gov/cdrh\\_docs/pdf11/p110014a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110014a.pdf)

[2] <http://www.merriam-webster.com/medlineplus/diagnostic>

[3] <http://www.merriam-webster.com/medlineplus/histopathology>

[4] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p110014>

[5] <http://www.nlm.nih.gov/medlineplus/breastcancer.html>