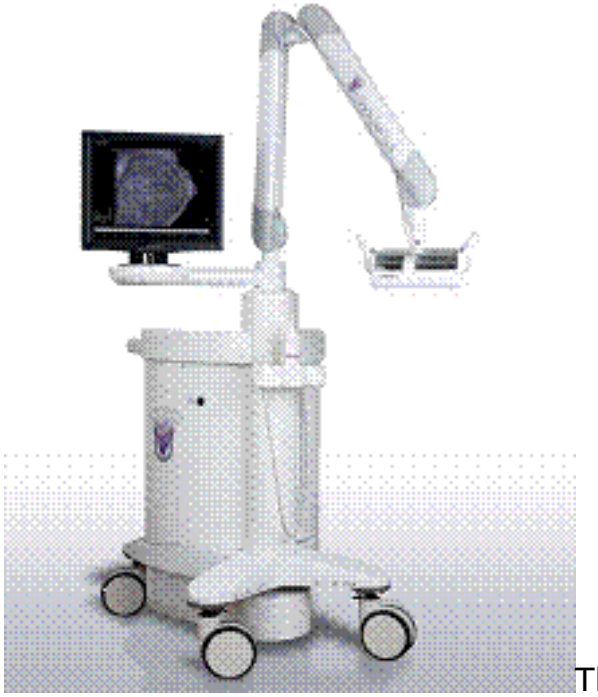
Consumer Information on: somo-v Automated Breast Ultrasound System (ABUS) - P110006

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: somo-v Automated Breast Ultrasound System (ABUS)
Manufacturer: U-Systems, Inc.
Address: 447 Indio Way, Sunnyvale, CA 94085
Approval Date: September 18, 2012
Approval Letter: http://www.accessdata.fda.gov/ cdrh_docs/pdf11/p110006a.pdf [1]

What is it? The somo-v Automated Breast Ultrasound System (ABUS) may be used to produce ultrasound images of the breast for breast cancer screening following a negative mammogram.

How does it work? The ABUS scans the entire breast. It has a workstation that allows physicians to review ultrasound images from different angles producing several images for review. The ultrasound imaging technology can help reveal hidden tumors in the dense breast tissue.

When is it used? The ABUS is intended for use in women with dense breasts who have negative X-ray mammography results and have not had previous invasive procedures, such as breast surgeries or biopsies.

What will it accomplish? The ABUS has been shown to detect small masses in dense breasts. This imaging device can help physicians review the ultrasound images of the entire breast for breast cancer screening.

When should it not be used? There are no known contraindications.

Additional Information: The Summary of Safety and Effectiveness Data and labeling [2] are available online.

Other Resources:

- FDA News Release [3]
- FDA - Office of Women's Health - Mammography [4]
- NIH - National Library of Medicine - Mammography [5]

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Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110006a.pdf
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