Consumer Information on: Breast Companion & #xae; Software System - P100007

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: Breast Companion® Software System
PMA Applicant: Almen Laboratories, Inc.
Address: 1672 Gil Way, Vista, CA 92084
Approval Date: February 10, 2012
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100007a.pdf [1]

What is it? The Breast Companion® Software System is a computer-aided report-generating system intended to improve the ACR BI-RADS® (American College of Radiology, Breast Imaging Reporting and Data System [2] [3]) assessment of ultrasound images of lesions of the female breast as part of the diagnostic workup.

The Breast Companion® Software System is an ACR BI-RADS® Companion™ with an added optional scoring function (Computer-aided Lesion Assessment, or CLA [4]) and is fully compliant with the ACR BI-RADS®.

How does it work? The radiologist performs a secondary review of the diagnostic ultrasound mammography images by selecting one or more lesion views to use in the ACR BI-RADS® assessment; and selects the area(s) on which to make the diagnosis. The radiologist may accept the automatic outline of the lesion image or may modify it with manual outlining. The Breast Companion® compares the selected lesion image with the automatic or manual outline to the most similar lesions retrieved from a Reference Library and computes the CLA score.

The radiologist proceeds with the ACR BI-RADS® Classification Form [5] [3]and selects the appropriate descriptors to assess the lesion. Before finalizing the assessment category, the radiologist may use the Breast Companion® CLA Scoring Process. Based on the computed CLA score, the radiologist may or may not change the ACR BI-RADS® Assessment.

When is it used? The radiologist may use the Breast Companion® CLA to complete an ACR BI-RADS® ultrasound diagnostic assessment report of a lesion that was detected or identified in a previous and independent procedure using a different imaging method such as screening mammography or physical examination and then imaged with ultrasound.

What will it accomplish? Breast Companion® may improve the ACR BI-RADS® assessment of ultrasound images of lesions of the female breast as part of the diagnostic workup.

When should it not be used? There are no contraindications for the use of this device.

Additional information: Summary of Safety and Effectiveness and labeling [6] are available at:

Other Resources:

- NIH-MedlinePlus-Mammography [7]

SOURCE [8]

Source URL (retrieved on *04/28/2015 - 8:17am*):
http://www.mdtmag.com/news/2012/03/consumer-information-breast-companion-xae-software-system-p100007

Links:
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