FDA Safety Notification: Mammography Problems at Medisound, Inc. in Kissimmee, Florida

U.S. Food & Drug Administration

Date Issued: August 27, 2010

Audience:

- Patients who had a mammogram at Medisound, Inc. in Kissimmee, Florida between June 10, 2008 and July 12, 2010.
- Health care providers who have referred patients to Medisound, Inc. facility for a mammogram performed between June 10, 2008 and July 12, 2010.

Medical Specialty: Primary Care, Oncology, Radiation

Product:
A mammogram is a safe, low-dose X-ray picture of the breast. It is currently the most effective method of detecting breast cancer in its earliest, most treatable stages.

Summary of Problem or Scope:
The FDA became aware of problems associated with the quality of mammograms performed at the Medisound, Inc. facility, located at the following address:
301 North John Young Parkway, Kissimmee, Florida 34741

The FDA worked with the American College of Radiology (ACR) as they initiated a review of a sample of mammograms performed by Medisound, Inc. that included images taken between June 10, 2008 and June 10, 2010. Results from that review included poor quality mammograms with possibly unreliable results. Under the Mammography Quality Standards Act (MQSA) of 1992, the FDA requires that all mammography facilities meet certain high quality standards. This facility did not meet standards for mammography quality under that Act. The facility no longer performs mammography due to a denial of its accreditation by the ACR.

The FDA is alerting patients who had mammograms at this facility between June 10, 2008 and July 12, 2010 about possible problems with the quality of mammograms performed. This does not mean that the results of all of the examinations were inaccurate. It does mean that patients might need to have their mammograms re-evaluated and possibly repeated.

Recommendations/Actions:
The FDA recommends the following for patients who had a mammogram at Medisound, Inc. facility between June 10, 2008 and July 12, 2010:

- If you have had a mammogram at another facility since then, you should follow the recommendations from the latest mammogram.
- If you have not had a mammogram at another facility since then follow these guidelines:
    - Talk with your current health care provider as soon as possible about a medical follow-up.
    - To request a copy of your mammogram performed by Medisound, Inc., call Milagios Vargas at 407-610-1894. If your health care provider wants you to have another mammogram, it should be done at a MQSA-certified facility to ensure quality and accuracy. A list of MQSA-certified facilities is available online [1].
    - If your health insurance will not pay for a repeat mammogram, you can call the National Cancer Institute's (NCI) information number at 1-800-422-6237 for a listing of facilities near you that will provide free or low- cost mammograms.

FDA Activities:
The agency will continue to monitor this problem and keep the public informed as new information becomes available.

This safety alert is in keeping with FDA's commitment to inform the public about safety issues.

Contact Information:
If you have questions about this communication, please contact the MQSA Hotline at 1-800-838-7715, email your question to MQSAhotline@hcmsllc.com [2] or fax to 1-410-290-6351.

SOURCE [3]

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[1] http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/ConsumerInformation/ucm113962.htm
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