FDA Safety Notification: Medisound, Inc./Digital Radiology Center, in Kissimmee, Florida Performing Mammography Without an MQSA Certificate

U.S. Food & Drug Administration

Date Issued:

Sept. 28, 2012

Audience:

- Patients who had a mammogram at Medisound, Inc./Digital Radiology Center facility in Kissimmee, Fla. any time after June 8, 2011.
- Health care providers who referred patients to the Medisound, Inc./Digital Radiology Center facility for a mammogram performed any time after June 8, 2011.

Medical Specialties:

Primary Care; Family Medicine; Internal Medicine; Obstetrics and Gynecology; Radiology

Product:

A mammogram is a 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 is alerting patients who had mammograms at this facility any time after June 8, 2011 about possible problems with the quality of mammograms performed. This does not necessarily mean that the results of the examinations were inaccurate. It does mean that patients need to have their mammograms re-evaluated and possibly repeated.

The FDA became aware of problems associated with the accreditation application of Medisound, Inc./Digital Radiology Center, located at the following address:

1105 Sumner Street
Kissimmee, Florida 34741

The FDA worked with the American College of Radiology during its review of the facility’s accreditation application and request to do business under a new name,

Digital Radiology Center. Information provided in the accreditation application indicated a link between the operators of Digital Radiology Center and Medisound, Inc, a former mammography provider that was the subject of an FDA Safety Notification [1] published on Aug. 27, 2010, which cited the facility for poor quality images and possible unreliable results.

On Sept. 6, 2012, the FDA and the Florida Department of Health conducted an inspection and found Digital Radiology Center had performed mammography while their facility was uncertified. Their facility also failed to perform required testing on its mammography equipment.

Under the Mammography Quality Standards Act (MQSA) of 1992, the FDA requires that all mammography facilities meet certain baseline quality standards and be certified to legally operate in the United States. This facility did not meet standards for mammography quality under that Act.

Recommendations/Actions:

The FDA recommends the following for patients who had a mammogram at Medisound, Inc./Digital Radiology Center any time after June 8, 2011.

- If you have had a mammogram at another facility since then, you should follow the recommendations from that facility.
- 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 the need for a follow-up exam.
    - To request a copy of your mammogram performed by Medisound, Inc./Digital Radiology Center, call (407) 519-8947. If your health care provider recommends you have another mammogram, it should be done at an MQSA-certified facility to ensure quality and accuracy. A database of MQSA-certified facilities is available online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm [2].
    - 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 FDA will continue to monitor this issue and keep the public informed as new information becomes available.

This safety notification is in keeping with the 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 [3] or fax to 1-410-290-6351.

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http://www.mdtmag.com/news/2012/09/fda-safety-notification-medisound-inc/digital-radiology-center-kissimmee-florida-performing-mammography-without-mqsa-certificate?qt-recent_content=0&qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224161.htm
[2] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm
[3] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/mailto:MQSAhotline@hcmsllc.com