



New Device Approvals

SenoScan® Full Field Digital Mammography System - P010017

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 and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: SenoScan® Full Field Digital Mammography System
Manufacturer: Fischer Imaging Corporation
Address: 12300 North Grant Street, Denver, Colorado 80241-3120
Approval Date: September 25, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p010017a.pdf>

What is it? Like regular mammography, digital mammography produces pictures of the breast using x rays, but instead of film, this process uses detectors that change the x-rays into electrical signals, which are then converted to an image. Digital mammography is used for both screening and diagnosis. For the patient, the procedure is the same as with ordinary mammography.

How does it work? The device passes x-rays through the breast tissue to a digital receptor, which converts the x-ray energy to numbers, processes the numbers, and produces an image that can be displayed on a monitor or printed on a high-resolution laser printer.

When is it used? The device is used in the same applications (screening and diagnosis) as regular analog (film) mammography.

What will it accomplish? The device has been shown to be effective in the detection of breast cancer and other abnormalities.

When should it not be used? For women who need mammographic screening or diagnosis, there are no reasons not to use this device.

Additional information: Summary of Safety and Effectiveness Data and labeling will be available at: <http://www.fda.gov/cdrh/pdf/p010017.html>

Other:

- General Consumer Information on Mammography
<http://www.fda.gov/cdrh/mammography/consumers-rev.html>
- Questions Consumers Frequently Ask About Digital Mammography
<http://www.fda.gov/cdrh/mammography/dig-faq.html#digital>
- FDA Consumer Magazine January-February 1999
http://www.fda.gov/fdac/features/1999/199_mamm.html
- FDA Consumer Magazine July-August 1999
http://www.fda.gov/fdac/features/1999/499_breast.html

(Updated 11/28/2001)