



New Device Approvals

Lorad Digital Breast Imager - P010025

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: **Lorad Digital Breast Imager**
Manufacturer: Hologic, Inc.
Address: 35 Crosby Drive, Bedford, MA 01730- 1401
Approval Date: March 15, 2002
Approval Letter: <http://www.fda.gov/cdrh/pdf/P010025a.pdf>

What is it? Like regular mammography, digital mammography produces pictures of the breast using x-rays. 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. The Lorad Digital Breast Imager (LDBI) is used with an approved x-ray system, the Lorad M-IV Mammography X-ray System, which was cleared by the FDA.

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

When is it used? The device is used to screen and diagnose breast cancer just 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 is available at:
<http://www.fda.gov/cdrh/pdf/P010025.html>

Other:

- "Questions Consumers Frequently Ask About Digital Mammography:
<http://www.fda.gov/cdrh/mammography/dig-faq.html#digital> "
- General Consumer Information on Mammography:
<http://www.fda.gov/cdrh/mammography/consumers-rev.html>

(Updated 04/18/2002)