Second Look™ - P010034

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:	Second Look™
Manufacturer:	CADx Medical Systems, Inc.
Address:	Parexel International Corporation, 195 West Street, Waltham, MA 02451-1163
Approval Date:	January 31, 2002
Approval Letter:	http://www.fda.gov/cdrh/pdf/p010034a.pdf

What is it? The Second Look™ is a Computer-Aided Detection (CAD) system used to help radiologists who read mammograms. The system uses special computing equipment and a special x-ray film scanner.

How does it work? The Second Look™, using the film scanner, changes the image of the mammogram into digital data. The Second Look™ uses these data to locate areas suspicious for cancer of the breast that might have been overlooked when the radiologist first reads the mammogram.

For a drawing of the breast with some expected disorders go to:

http://www.medem.com/MedLB/article_detaillb.cfm?article_ID=ZZZ3F9G56JC&sub_cat=326

When is it used? Before making a final patient diagnosis, the radiologist must first review each mammogram as usual and then re-examine the original films observing any suspicious areas marked by the Second Look™. This way, the Second Look™ reduces the number of missed cancers. This system can be used with any standard film/screen mammographic views.

What will it accomplish? Research studies have shown that the Second Look™ helps the radiologist detect cancers that might otherwise have been overlooked. The Second Look™ does increase the need for patients to have additional x-ray views, ultrasound examinations, and biopsies. Medical personnel, however, see this increase as acceptable since there is also an increase in cancers identified.

Although the Second Look™ alerts a radiologist to additional suspicious areas missed on the mammogram, the device may also fail to mark areas the radiologist identified on the mammogram. If this occurs, the radiologist is cautioned not change his or her decision about the suspicious areas he or she identified on the mammogram.

When should it not be used? There are no contraindications for this device. The key warnings for radiologists who use this device are the following:

- review the films in the usual manner first, before reviewing the Second Look™ system results;
- do not be discouraged from taking further action regarding a suspicious breast area simply because the Second Look™ did not mark that region;
- since most marked locations do not indicate cancer, decide if further action is required based on the reading of the mammogram - after examining the areas marked by the Second Look™; and
- remember that the Second Look™ aids in detecting suspicious areas for re-examination; it is not the primary basis for decisions on those areas.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p010034.html

Other:

- Information on a similar device: MammoReader - P010038
- Information on digital mammography
  http://www.fda.gov/bbs/topics/ANSWERS/ANS01000.html
  http://newscenter.cancer.gov/pressreleases/acrin.html
- General information on mammography:
  http://www.nlm.nih.gov/medlineplus/mammography.html

(Updated June 19, 2002)