RapidScreen™ RS-2000
P000041

Product Name: RapidScreen™ RS-2000
Manufacturer: Deus Technologies, LLC
Address: 1700 Research Blvd., Rockville, MD 20850
Approval Date: July 12, 2001
Approval Letter: http://www.fda.gov/cdrh/pdf/p000041a.pdf

What is it? The device is a computer-aided detector used when viewing the chest x-rays of patients at high risk of lung cancer. It improves the ability to locate single, nodule-like growths in the lungs that could be lung cancer. The system finds suspicious areas that may contain cancer and brings them to the doctor's attention after he/she has already examined the x-ray.

How does it work? The device digitizes the chest image, processes it, and produces a picture with the suspicious areas highlighted by circles.

When is it used? The device assists the doctor in interpreting chest x-rays of patients who have an increased risk of lung cancer by identifying areas containing a potential lesion that otherwise may have been missed.

What will it accomplish?

- The RS-2000 system can help detect single small nodular growths in the lungs in chest x-rays, an important indication of early-stage lung cancer.
- The system has been shown to be effective in men over 45 years of age with increased risk for lung cancer due to smoking. The effectiveness of the system has not been evaluated with other groups.
- Physicians using the RS-2000 system can increase their ability to find small (9-30 mm) lung cancers on chest x-rays. According to the American Cancer Society, only 15 percent of such cancers can be detected without this kind of computer help.

When should it not be used? The device is of little value when used for patients who are not at high risk

for lung cancer.

Additional information:

- Summary of Safety and Effectiveness and labeling will be available at: http://www.fda.gov/cdrh/pdf/p000041.html

Other: http://www.cancer.org/

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