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K110025

510(k) Summary (21 CFR 807.92)

APR 2 8 2011

A. SUBMITTER INFORMATION

Submitter's name	Sectra Imtec AB
Address	Teknikringen 20 SE-583 30 Linköping Sweden
Establishment registration number	9615992
Contact person	Alexander Asklöv
Telephone	+46-13-23 52 00
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Title	Chief Quality Officer of product division mammography at Sectra Imtec AB
Date of the summary preparation	2010-12-30

B. DEVICE IDENTIFICATION

Device trade name	Sectra MicroDose Mammography L30
Device common name	Full-Field Digital Mammography X-ray System
Classification name	Full-Field Digital Mammography X-ray System
Classification product code	MUE
Device class	II
Regulation code	21 CFR 892.1715

C. DEVICE DESCRIPTION

The Sectra MicroDose Mammography L30 is a type of full-field digital mammography system comprised of an image acquisition system, a gantry and an acquisition workstation computer equipped with a keyboard, a keypad, a mouse, and a monitor. The image acquisition system includes a digital detector of photon counting technology, x-ray tube (with tungsten target and aluminum filtration), high voltage generator, compression paddle(s), and multi-slit collimator. The acquisition workstation is the user interface for preparing and initiating image acquisition, image processing, and image transfer to the desired destination (e.g. PACS) for diagnosis and archiving.

The Sectra MicroDose Mammography L30 detector is based on photon counting technology and consists of a large number of crystalline silicon strip detectors. The technology enables high detection efficiency of photons and efficient rejection of electronic noise. The Sectra MicroDose Mammography L30 uses a multi-slit scanning technique that prevents image degradation caused by scattered radiation by removing photons scattered in the breast and not directed towards the detector. These factors combine into a dose efficient system.
The Sectra MicroDose Mammography L30 provides three exposure modes; manual, automatic (parameters predefined based on compressed breast thickness), and SmartAEC. SmartAEC

continuously adjusts the exposure based on measured transmission from the leading detector edge.

D. INDICATIONS FOR USE

The Sectra MicroDose Mammography L30 is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Sectra MicroDose Mammography L30 is intended to be used in the same clinical applications as traditional film/screen systems.

E. PREDICATE DEVICES

	Predicate device #1	Predicate device #2
Trade Name	FUJI'S COMPUTED RADIOGRAPHY MAMMOGRAPHY SUITE (FCRMS)	SENOGRAPHE 2000D
Classification Name	Full Field Digital, System, X-ray, Mammographic	Full Field Digital, System, X-ray, Mammographic
Generic Name	Fuji CR-IR348CL Image Console With FCRMS Software	Digital Mammographic X-ray System
PMA Applicant	FUJIFILM MEDICAL SYSTEM U.S.A., INC.	GE HEALTHCARE
PMA Number	P050014	P990066
Product Code	MUE	MUE
Advisory Committee	Radiology	Radiology

F. TECHNICAL CHARACTERISTICS

The Sectra MicroDose Mammography L30 System does not employ exactly the same type of detector as the predicate devices and the readout methods are different, however the fundamental process of digital full field mammographic image creation remains the same for all three devices; x-ray photons are captured in the detector and ultimately converted to an electrical signal, forming a digital image.

Performance data from non-clinical testing of the Sectra MicroDose Mammography L30 covering Sensitometric response, Spatial resolution, Noise analysis, Signal-to-noise-ratio transfer – DQE, Dynamic range, Automatic exposure control performance, Phantom testing, Patient radiation dose, and Image erasure, fading and repeated exposure was compared with data from the PMA Summary of Safety and effectiveness of the predicate devices. This comparison showed that the Sectra MicroDose Mammography L30 device performed as well as or better than the predicate devices in all relevant areas. The testing was performed in accordance with generally accepted test methods, e.g. using IEC standards, published factors for dose calculations etc.

An image attribute evaluation was conducted in accordance with the *Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Full-Field Digital Mammography System* [issued: November 5, 2010] which concluded that the images were of sufficiently acceptable quality for clinical mammographic usage.

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G. CONCLUSION

The Sectra MicroDose Mammography L30 described in this submission is substantially equivalent to the predicate devices in respects of indication for use and image quality. The proposed and predicate devices utilize similar technology and materials, comparable safety and effectiveness features, and are similar in design and construction. The information submitted in this application shows that none of the technical differences between the systems raises new questions of safety and effectiveness. All collected performance data demonstrate that the devices are substantially equivalent. Our conclusion is that Sectra MicroDose Mammography L30 is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Alexander Asklöv
Chief Quality Officer
Sectra Imtec AB – Product Division Mammography
Teknikrigen 20
Linköping SE-58330
SWEDEN

APR 2 8 2011

Re: K110025
Trade/Device Name: Sectra MicroDose Mammography L30
Regulation Number: 21 CFR 892.1715
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: MUE
Dated: April 15, 2011
Received: April 19, 2011

Dear Mr. Asklöv:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110025

Device Name: Sectra MicroDose Mammography L30

Indications for Use: The Sectra MicroDose Mammography L30 is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer.
The Sectra MicroDose Mammography L30 is intended to be used in the same clinical applications as traditional film/screen systems.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110025

Page _1_ of _1_