INSTRUMENTARIUM imaging

13 November 2002 K023864

510(K) SUMMARY

JAN 0 9 2003

MANUFACTURER:

Instrumentarium Corp. Imaging Division
P.O.Box 20 (Street Address: Nahkelantie 160)
FIN-04301 Tuusula, Finland

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Contact person: Kaija Jokela

UNITED STATES SALES REPRESENTATIVE (U. S. DESIGNATED AGENT):

Instrumentarium Imaging Inc.
300 West Edgerton Avenue
Milwaukee, Wisconsin 53207

Phone: 414-747-1030
Fax: 414-481-8665

PRODUCT, CLASSIFICATION NAME

Performa Stereo (Film stereotactic biopsy and lesion marking system)

System, x-ray, mammographic/ IZH

Regulation number: 892.1710

SUBSTANTIAL EQUIVALENCE:

We consider this product is similar in design, composition and function to the following devices introduced into commercial distribution after May 28, 1976:

Alpha Stereo 4	#K934478
GE Stereotix 2	#K941191
Siemens Mammomat 3000 Stereo	#K884107

The comparison of characteristics supports substantial equivalence. The Performa Stereo integrates the features of the predicate device Alpha Stereo 4 to the new platform Performa.

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DESCRIPTION:

Performa Stereo is a breast biopsy and lesion marking system in connection with the Performa mammographic system (#K981641). The Performa stereo is especially developed for fine needle aspiration (FNA), core biopsy, vacuum assisted biopsy and lesion marking. The Performa Stereo system consists of a biopsy unit with a needle guide and a breast support table, an adapter unit for making ±15° angles, and a film marker unit. A mechanical docking interface is used for connecting the Performa Stereo's stereo adapter and the biopsy unit together. There are no electrical connections between the biopsy unit and Performa.

The adapter unit is identical to adapter used in the case of Alpha Stereo 4 and Delta 16. The needle guide is a Cytoguide biopsy unit which is the same than used in the case of Delta 32.

In an examination two X-ray images are taken at angles of +15° and -15° degree of the region of interest in the breast. The image capturing will be made by 18x24 cm film cassette and the needle targeting driving will be made with the motorized Cytoguide needle guide unit which are the main functions of the biopsy unit. After making two individual stereotactic X-ray exposures to one film, the corresponding two images are shown side by side on the film reader unit. The user then marks the target point with a cursor on each image. Based on the marking the xyz-coordinates of target are calculated by the film marker unit. The needle holder is then automatically positioned, taking into account the coordinate information and the needle length selected. The tip of the needle, which is then inserted into the holder with correct bushings can now be used to penetrate the lesion area.

INTENDED USE:

Performa Stereo is intended to be used for breast biopsy or lesion marking with the base mammographic system Performa with stereo adapter.

Instrumentarium Corp. Imaging Division

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Regulatory Affairs
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 9 2003

Instrumentarium Corp. Imaging Division
% Mr. Brian Broncatti
Instrumentarium Imaging, Inc.
300 West Edgerton Avenue
MILWAUKEE WI 53207

Re: K023864
Trade/Device Name: Performa Stereo
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: November 13, 2002
Received: November 20, 2002

Dear Mr. Broncatti:

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 either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INSTRUMENTARIUM imaging

13 November 2002

510(k) Number (if known): _____

Device Name: Performa Stereo

Indications for Use: Performa Stereo is intended to be used for breast biopsy or lesion marking with the base mammographic system Performa with stereo adapter.

Instrumentarium Corp. Imaging Division

Kaija Jokela
Regulatory Affairs

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

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use ✓

David A. Lieppman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023864

(Optional Format 3-10-98

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