510(K) SUMMARY

SEP 12 2002

MANUFACTURER:

Instrumentarium Corp. Imaging Division
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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

Delta 32 with optional add-on TACT®
(Diagnostic digital mammography spot and 3D imaging, optional to digital stereotactic breast biopsy, 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:

Delta 32 and Delta 32 Tact®	#002472
Diamond	#000976

The technological characteristics of Delta 32 and Delta 32 TACT® are the same than in the previous application (#K002472). This application shows that Delta 32 and Delta 32 TACT® can also be used for diagnostic examinations like Diamond (#K000976).

DESCRIPTION:

Delta 32 and Delta 32 TACT® is a mammographic diagnostic digital mammography spot and 3D imaging system, which can also be used for digital stereotactic breast biopsy. The base system is the Diamond mammographic system (#K955411), on which the Delta 32 and Delta 32 TACT® is installed.

The images are acquired by a CCD camera identical to our Delta 32 (#K002472). The needle guiding system is the same than previously, Cytoguide biopsy unit (#K885020). A PC workstation receives images and computes the necessary needle coordinates for Cytoguide unit. The PC also performs the optional TACT® 3D reconstruction identically to the Delta 32 TACT® system described in (#K002472). The PC workstation can also be used as stand-alone for viewing digital mammography spot and 3D images taken by Delta 32 and Delta 32 TACT®.

INTENDED USE:

Delta 32 and Delta 32 TACT® are intended to be used for diagnostic digital spot and 3D imaging, and optionally for digital stereotactic breast biopsy. Delta 32 and Delta 32 TACT® are intended to be used with the base mammographic system Diamond. However, a PC workstation of Delta 32 and Delta 32 TACT® can also be used as stand-alone for viewing images taken by Delta 32 and Delta 32 TACT®. The TACT® add-on provides means for digital 3D spot imaging using 2D projection images acquired with the system.

PERFORMANCE DATA:

The evaluation of Delta 32 and Delta 32 TACT® for diagnostic use is based on the clinical study. The evaluation has been done by comparing the clinical diagnostic image quality of the three-dimensional mammography system and digital diagnostic spot mammography system to screen and diagnostic film system in terms of subjective image quality. The Likert scale was used from +4 to –4, where +4 means that digital image was absolute better than film image and –4 that film image was absolute better than digital image. Digital 3D mammography imaging (TACT®), digital spot mammogram (DSM), screen-film mammography imaging (SFM) and diagnostic film imaging (DFM) exams were performed on 60 symptomatic cases (female, age from 46 to 63).

Following table summaries the result of the tests:

(N=180)	Average	Std. Error	t-test
TACT® 3D slices vs. DFM images	0.82	0.15	p<0.0001
DSM against DFM images	0.64	0.13	p<0.0001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2002

Instrumentarium Corp.
Imaging Division
% Mr. Mark Masson
Quality Regulatory Coordinator
Instrumentarium Imaging, Inc.
300 West Edgerton Avenue
Milwaukee, Wisconsin 53207

Re: K022275
Trade/Device Name: Delta 32 with optional add-on TACT
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: July 10, 2002
Received: July 15, 2002

Dear Mr. Masson:

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

10 July 2002

Indications for Use

510(k) Number (if known): K022275

Device Name: Delta 32 with optional add-on TACT®

Indications for Use:

Delta 32 and Delta 32 TACT® are intended to be used for diagnostic digital spot and 3D imaging, and optionally for digital stereotactic breast biopsy. Delta 32 and Delta 32 TACT® are intended to be used with the base mammographic system Diamond. However, a PC workstation of Delta 32 and Delta 32 TACT® can also be used as stand-alone for viewing images taken by Delta 32 and Delta 32 TACT®. The TACT® add-on provides means for digital 3D spot imaging using 2D projection images acquired with the system.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022275

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

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