510(K) SUMMARY

PRODUCT, CLASSIFICATION NAME

Delta 16 TACT® (Mammographic 3D spot imaging system)

System, x-ray, mammographic/ IZH

Regulation number: 892.1710

MANUFACTURER:

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

Phone: +358-10-394 6500
Fax: +358-10-394 6501

Contact person: Tommi Jokiniemi

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

INTENDED USE:

Delta 16 TACT® is intended to be used for digital 3D spot imaging using 2D projection digital spot mammographic images acquired with Delta 16.

DESCRIPTION:

Delta 16 TACT® is a spot imaging system. The base system is the Delta 16 biopsy and spot system (#K955411) acquiring two-dimensional digital images. Based on these, the TACT® algorithm reconstructs three-dimensional images for further use.

The TACT® method (Tuned Aperture Computed Tomography) uses the Delta 16 system to acquire a number of two-dimensional digital images of the breast from different angles without moving the breast. A patented reference point in each image defines the image geometry and a three-dimensional model of the breast can then be reconstructed. Using the reference point means that

accuracy comes from the images, not from the system mechanics as in conventional CT, for example.

When acquiring images for the reconstruction, every image adds information to the final result. Therefore it is possible to divide the total exposure equally between all images. This results in comparable patient dose to one conventional digital image, but with more information acquired - the third dimension.

The three-dimensional image can be viewed in ways that have not been available before. The volume can be viewed in slices whose thickness is user-defined. These viewing possibilities truly allow the user to overcome the largest problems in mammography - imaging of dense breasts or having the place of interest overlaid by other structures in the breast.

SUBSTANTIAL EQUIVALENCE:

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

Delta 16 # K955411

The physical characteristics of the fully operational systems are identical. The Delta 16 TACT® is an add-on workstation for TACT slice reconstuction from 2D projection images acquired with the Delta 16 base system.

The intended uses are essentially equivalent: The intended use of Delta 16 includes spot imaging and the Delta 16 TACT® is intended for 3D spot imaging. The only difference is that the TACT® system is capable of viewing the imaged volume in slices thinner than the compressed breast thickness.

PERFORMACE DATA

The technical comparison tests between the Delta 16 and the Delta 16 TACT® have shown that the linepair resolution and contrast of TACT® images is better than or comparable to the base system Delta 16 without the TACT® add-on.

The clinical tests have shown that in most cases the TACT® images provided additional information in the areas of interest with enough contrast and resolution to provide valuable diagnostic information for clinical work. In all cases the TACT images provided information that was at least equivalent to the Delta 16 single projection images. The third dimension added by the TACT® algorithm has proven useful for mammography.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Instrumentarium Imaging, Inc.
C/o Max Lindert
300 West Edgerton Avenue
Milwaukee, Wisconsin 53207

Re: K001171
Delta 16 TACT
Dated: April 5, 2000
Received: April 11, 2000
Regulatory Class: II
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. Lindert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001171

Device Name: Delta 16 TACT

Indications For Use:

Delta 16 TACT® is intended to be used for digital 3D spot imaging using 2D projection digital spot mammographic images acquired with Delta 16.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001171

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)