5 510(k) Summary Compass K072374

5.1 510(k) owner

Scanditronix Wellhöfer GmbH
Bahnhofstrasse 5
90592 Schwarzenbruck
Germany

Tel: +49 9128 607 0
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DEC 07 2007

5.2 Contact person

Martin Arold

5.3 Preparation date

15/08/2007

5.4 Trade name

Compass

5.5 Common name

Accelerator, linear, medical

5.6 Classification name

Medical charged-particle radiation therapy system (21 CFR 892.5050, Product Code IYE)

5.7 Predicate devices

K062817 David (PTW), K031634 OmniPro I'mRT (Scanditronix Wellhöfer),
K012227 muCheck (Oncology Data Systems, Inc.), Delta^4 (Scandidos AB)

5.8 Device description

The system is intended to be used with intensity modulated radiation therapy, delivered with high energy x-ray beams from an isocentric gantry linear accelerator. The modulation of these beams shall be accomplished by means of MLCs and Jaws.

The aim is to measure the fluences of the applied fields by means of electronic 2D devices, including transmission detector which can be used during patient irradiation. Alternatively the fluences can be calculated from a computation independent from the original TPS, using segmentation data from the TPS or a delivery log file.

Furthermore, the intention of the system is to recalculate the resulting dose distribution in a

phantom or, using patient anatomy data, in a patient.

Moreover, the system allows performing QA tests on the radiation delivery system. When the system is used together with electronic 2D devices, preferably with transmission detector, it can also provide sensitivity calibration and performance tests on EPID systems.

Finally, the system will provide online information about the quality of the delivery, both on a delivery system level (e.g. leaf positioning accuracy, dose per segment accuracy) as on the patient level (resulting dose distribution). In case of discrepancies, corrective action (adjusted plan for further fractions) shall be proposed.

5.9 Intended use

COMPASS is used for

quality assurance and plan verification in external beam radiation therapy for multileaf collimated fields and intensity modulated fields.

It computes dose (energy per volume deposited by ionizing radiation) three-dimensionally in a geometrical representation of a patient or a phantom. The calculation is based on read-in treatment plans, and additionally on online or offline measurements of radiation fields with radiation-transparent or non-transparent, 2 dimensional multi-element ionization chamber arrays.

5.10 Technological characteristics summary

On principle, all devices allow performing QA tests on the radiation delivery system.
Based upon the technological characteristics, intended use, and non-clinical tests, Compass is substantially equivalent to the predicate devices. The documentation submitted for review supports this claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2007

Mr. Martin Arold
Quality Manager
IBA Dosimetry GmbH
Bahnhoftrasse 5, 90592 Schwarzenbruck
GERMANY

Re: K072374
Trade/Device Name: Compass
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy device
Regulatory Class: II
Product Code: IYE
Dated: November 15, 2007
Received: November 20, 2007

Dear Mr. Arold:

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 such 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 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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K072374

Device Name: COMPASS

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quality assurance and plan verification in external beam radiation therapy for multileaf collimated fields and intensity modulated fields.

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 and Radiological Devices
510(k) Number K072374