JAN 6 2006

510(k) Summary K052682

As required by 21 CFR 807.92

1 Owner

Vision RT Ltd
Daws House
33–35 Daws Lane
London NW7 4SD
United Kingdom

Principle Contact:
Dr Norman Smith
Chief Executive Officer
Tel: +44 (0)20 8906 6620
Fax:+44 (0)20 8906 6621
Email: nsmith@visionrt.com

2 510(k) Summary Preparation Date

July 19, 2005

3 Device Details

Name
AlignRT

Common Name
Radiotherapy positioning system

Classification Name
System, radiation therapy, charged-particle
Product code: LHN
Regulation: 21 CFR 892.5050

4 Predicate Devices

Exactrac system (K983660) and,
Osiris system (K981153).

5 Device Description

AlignRT is a video-based three-dimensional (3D) surface imaging system, which is used to image the skin surface of a patient in 3D before and

during radiotherapy treatment. The system consists of advanced software, a computer workstation, two 3D camera units, cables, and templates that are used for camera calibration. The system is non-invasive, does not require the use of body markers and produces no irradiation during the imaging process.

AlignRT first generates a reference surface of the optimum treatment position determined during treatment simulation. This reference image is generated by either recording the surface of a patient placed in a conventional radiotherapy simulator in which the system is installed or by importing skin contours from CT (X-Ray Computer Tomography) volumetric data generated via third party treatment planning software. Prior to each treatment session the patient's position is imaged and compared to the reference image by the system's surface matching software. Where movement from the reference position is detected the software calculates new co-ordinates to adjust the treatment couch for optimal positioning of the patient. The system is designed to interface directly with certain third party couch control systems.

In order to minimise the setup errors that can result from respiratory motion, an option is available to gate the image capture of the system so that all data is acquired at a repeatable point within the breathing cycle such as the end of exhalation.

Real-time imaging (1 frame/sec) of the patient is possible during the actual treatment and software verification tools are provided in order to determine any patient movement.

Patient contour data may be extracted from surface data acquired by the system. In addition, lung contour data may be estimated by utilising AlignRT 3D surface data and 2D X-ray data acquired from either a conventional simulator or portal imager. These data may be exported for the purpose of treatment planning by radiotherapy professionals.

5 Indications for Use

The AlignRT system is used to position patients at the isocentre of the linear accelerator for radiation therapy procedures. Patient contour data can be extracted and exported from the acquired data for the purpose of treatment planning.

AlignRT is used by radiotherapy professionals in appropriate hospital environments. It can be used with all types of radiotherapy patients and can image any visible anatomical region. The system is completely non-

invasive and does not require the application of any external markers to the patient.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

6 Comparison of Technological Characteristics

The AlignRT system is substantially equivalent to the predicate devices in terms of their intended use and technological characteristics. There are differences between the Align RT and predicate devices in terms of their principles of operation, materials, performance, human factors and energy delivered by the system. However, performance data has been submitted to show that AlignRT achieves its intended use and that these technological differences raise no new efficacy or safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Vision RT Ltd.
%Mr. Ned Devine
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K052682
Trade/Device Name: AlignRT
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 20, 2005
Received: December 22, 2005

Dear Mr. Devine:

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 (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 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 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" (21 CFR 807.97). 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) 443-6597 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): K052682

Device Name: AlignRT

Indications for Use:

The AlignRT system is used to position patients undergoing external beam radiation therapy. Prior to each treatment session the patient is registered to the position which best reproduces the patient's position during treatment simulation. The system can also monitor the patient's position during treatment so that movements from the optimum position can be detected. Patient contour data can be extracted and exported from the acquired data for the purpose of treatment planning by radiotherapy professionals.

AlignRT is used by radiotherapy professionals in appropriate hospital environments. It can be used with all types of radiotherapy patients and can image any visible anatomical region.

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)

David A. Jogerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052682