510(K) SUMMARY

AccuChanger

MAY - 5 2005

510(k) Number K 043409

Applicant's Name:

Direx Systems Corp.
11 Mercer Road, Natick Business Park
Natick, MA 01760
United States of America

Contact Person:

Larisa Gershtein
Direx Systems Corp.
11 Mercer Road, Natick Business park
Natick, MA 01760
United States of America
Tel: (508) 6510900
Fax: (508) 6518125

Trade Name:

AccuChanger

Model:

AccuChanger

Classification Name:

Accelerator, Linear, Medical

Classification:

The FDA has classified this type of devices as class II (product code IXI, Regulation No. 892.5710). They are reviewed by the Radiology Panel.

Establishment Registration Number

1224828

Predicate Devices:

The predicate devices for substantial equivalence are:

1. *AccuLeaf* k040553, DIREX Systems Corp.
2. *Cranial Stereotactic Equipment, k010065 Arplay/BrainLab*
3. XKnife K912630, Radionics Software Applications, Inc.,

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

However, *AccuChanger* complies with these voluntary standards:

IEC 60601-1 (2000);
IEC 60601-1-1 (2000);
IEC 60601-1-2 (2001);

IEC 60601-1-4, Ed. 1.1 (2000).

Intended Use:

AccuChanger is intended to assist the radiation oncologist in the delivery of radiation to well defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

In this application the *AccuChanger* performs the same function as customized beam shaping blocks, and circular or cut blocks collimators, which have been used for many years.

Device Description:

AccuChanger device is designed to be used for the Linac beam shaping during radiotherapy. It constitutes an add-on to a Linac used for automatic switching of circular collimators during treatments without entering the treatment room.

AccuChanger uses a two-level circular-collimator set. It has two drums one mounted on top of the other. Each drum has nine collimators arranged in a descending order of radius. Although it is possible for the collimation to combine any pair of collimators one from each drum, only seventeen combinations are deemed valid. Each valid combination is forming a circular aperture whereby one of the circular collimators (upper/lower) is set as the beam shaping collimator, the other (lower/upper respectively) is set as a post/pre bounding "protecting" collimator to reduce radiation transmission.

To start a treatment, a treatment file is needed specifying the aperture diameter at the isocenter for each of the treatment beams (defined input format). *AccuChanger*-CS calculates the fitting collimator size on one drum and chooses the best match on the other. Since the matching pairs are known in advance, a lookup table is used obviating the need of re-calculating the appropriate collimators pair.

Substantial Equivalence:

We claim *AccuChanger* to be SE to:

1. *AccuLeaf* k040553, DIREX Systems Corp.

It has identical intended use and indications for use as *AccuLeaf.*

2. *Cranial Stereotactic Equipment, k010065 Arplay/BrainLab*

3. XKnife K912630, Radionics Software Applications, Inc.,

All compared devices have similar principles of operation and technological characteristics. Furthermore, *AccuChanger* does not present any new method of treatment other than its predicate devices. Any minor differences between the systems do not raise new types of safety or effectiveness issues, as further discussed below.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

Ms. Larisa Gershtein
QA Manager
DiREX Systems Corp.
11 Mercer Road
NATICK MA 01760

Re: K043409
Trade/Device Name: AccuChanger
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 14, 2005
Received: April 18, 2005

Dear Ms. Gershtein:

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

AccuChanger

Indications For Use

510(k) Number (if known): k043409

AccuChanger is intended to assist the radiation oncologist in the delivery of radiation to well defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for the collimation of megavoltage photon beams in conjunction with Stereotactic Radio Surgery (SRS) and Stereotactic Radio Therapy (SRT) treatments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ And (Per 21 CFR 801.109)

Over-The-Counter Use

(Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043409