APR - 1 2004

510(K) SUMMARY

AccuLeaf

510(k) Number K 040553

Applicant's Name:

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

Contact Person:

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

Trade Name:

AccuLeaf

Model:

AccuLeaf

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:

1. *AccuLeaf* v1.03 K021338 cleared on January 07, 2003
2. BrainLAB MMLC (k970586)

Performance Standards:

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

However, *AccuLeaf* complies with these voluntary standards:

IEC 60601-1 (1990) +A1 (1993) +A2 (1995);
IEC 60601-1-1 (2000);
IEC 60601-1-2 (1993);
IEC 60601-1-4, Ed.1.1 (2000).

Intended Use:

AccuLeaf 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.

AccuLeaf enables irregular fields treatments to be performed with finely shaped patterns. In this application the *AccuLeaf* performs the same function as customized beam shaping blocks, and circular or cut blocks collimators, which have been used for many years.

Device Description:

AccuLeaf is a LINAC based Micro-Multi-Leaf-Collimator (MMLC), used in radiation treatment.

It enables shaping the Linac beam according to target geometrical and clinical requirements.

The device is composed of the MMLC module, the Linac interface module, the Workstation (with *AccuLeaf* Control Software), and the Distribution module.

The device operates in conjunction with a Linac, a treatment couch, and any additional equipment required in radiation treatment.

The MMLC apertures, (defined in treatment data file), are generated by positioning the motor-driven leaves. The motors, controlled by *AccuLeaf*, bring the leaves to specified positions. The *AccuLeaf* control operates as a sequential linear process, where the apertures are performed one by one.

To form a desired aperture, AccuLeaf calculates leaves motion from knowledge of their current positions (measured) and desired destination (delivered by treatment plan).

AccuLeaf displays an image reflecting the leaves current position. Numeric indication of each leaf position is available.

AccuLeaf two operation modes are Step-and-Shoot and Dynamic Arc:

- Step-and-Shoot: MMLC modifies the apertures prior to irradiation.

- Dynamic Arc: Irradiating Linac forms an arc while AccuLeaf forms apertures at a set of Gantry angles.

Substantial Equivalence:

The predicate devices for substantial equivalence are:

1. *AccuLeaf* v1.03 (k021338)
2. BrainLAB MMLC (k970586)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Sean Kelly
Chief Operating Officer
DiRex Systems Corporation
11 Mercer Road
NATICK MA 01760

Re: K040553
Trade/Device Name: AccuLeaf
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beamshaping block
Regulatory Class: II
Product Code: 90 IXI
Dated: February 26, 2004
Received: March 2, 2004

Dear Mr. Kelly:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the 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" (21CFR Part 807.97) you may obtain. 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040553

Device Name:

AccuLeaf

Indications for Use:

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

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

510(k) Number K040553

Prescription Use ✓ OR Over the Counter Use_____

(Per 21 CFR 801.109)

Edward A. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040553