JUL 2 3 2007

## SECTION 5 – 510(K) SUMMARY

### *TrackLeaf-10*

**510(k) Number K 071701**

**Applicant's Name:**

Direx Systems Corp.
437 Turnpike Street
Canton, MA 02021
United States of America
Tel: (339) 502 6013
Fax: (339) 502 6018

**Contact Person:**

Ms. Larisa Gershtein
E-mail: lgershtein@direxusa.com

**Trade Name:**

***TrackLeaf***

**Model:**

***TrackLeaf-10***

**Classification Name:**

Accelerator, Linear, Medical

**Classification:**

The FDA has classified this type of devices as class II (product code IYE, Regulation No. 892.5050). They are reviewed by the Radiology Panel.

**Establishment Registration Number**

1224828

**Predicate Devices:**

1. DART-12 (K052705) cleared on February 21, 2006
2. AccuLeaf v 2.1 (K040553) cleared on April 01, 2004

**Performance Standards:**

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

However, *TrackLeaf* complies with these voluntary standards:

- IEC 60601-1(1988) +A1 (1991) +A2 (1995)
- IEC 60601-1-1 (2000)
- IEC 60601-1-2 (2001)
- IEC 60601-1-4 (1996)+A1(1999)

**Intended Use:**

*TrackLeaf-10* 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.

*TrackLeaf-10* is a tertiary Micro Multi Leaf Collimating (MMLC) system. It performs the same functions as beam shaping blocks, circular or cut blocks collimators for Conformal and "step and shoot IMRT" treatments, and it also performs "dynamic arcs" and "dynamic IMRT" treatments.

**Device Description:**

*TrackLeaf 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 *TrackLeaf* Control Software), and the Power Distribution module.

The device operates in conjunction with a Linac, a treatment couch, a data file that contains the desired aperture parameters, and any additional equipment required in radiation treatment. ***In*** **addition, means are provided to receive aperture offset data from an Image Guided Radiation Therapy (IGRT) system in order to perform leaves position adjustments.**

MMLC apertures are generated by positioning the motor-driven leaves. T*rackLeaf* software operates as a sequential process of forming apertures.

*TrackLeaf* operation modes are: Step-and-Shoot, Dynamic Arc, and dynamic IMRT (DIMRT).

- Step-and-Shoot: *TrackLeaf* forms apertures while irradiation is off and gantry is stationary.
- Dynamic Arc: *TrackLeaf* forms apertures while irradiation is on and the gantry rotates.
- DIMRT: *TrackLeaf* forms apertures while irradiation is on and the gantry is stationary.

**Substantial Equivalence:**

*TrackLeaf* is substantially equivalent to its predicate devices since the intended use is unchanged and the basic features are the same or similar. The differences in added features between *TrackLeaf* and its predicate devices raise no issue of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 23 2007

Ms. Larisa Gershtein
QA Manager
Direx Systems Corporation
437 Turnpike Street
CANTON MA 02021

Re: K071701
Trade/Device Name: *TrackLeaf-10*
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 14, 2007
Received: June 21, 2007

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

DiREX
SYSTEMS CORP.

## SECTION 4: INDICATIONS FOR USE STATEMENT

# Indications for Use Statement

510(k) Number (if known): K071701

Device Name:

*TrackLeaf-10*

Indications for Use:

*TrackLeaf-10* 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.

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Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR § 801.109)

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

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K071701

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