FEB 2 1 2006

SECTION 7 – 510(K) SUMMARY

DART-12

510(k) Number K052705

Applicant's Name:

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

Tel: (888) 874 7837
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Contact Person:

Ms. Larisa Gershtein
Direx Systems Corp.
11 Mercer Road
Natick, MA 01760
Tel: (888) 874 7837
Fax: (508) 651-8125

E-mail: lgershtein@direxusa.com

Trade Name:

DART-12

Model:

DART-12

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. AccuLeaf v 2.1 (k040553) cleared on April 01, 2004
2. BrainLAB MMLC (k020860)

Performance Standards:

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

However, *DART-12* complies with these voluntary standards:

- IEC 60601-1(1988) +A1 (1991) +A2 (1995)
- IEC 60601-1-1 (2000)
- IEC 60601-1-2 (2004)
- IEC 60601-1-4 (2000)

Intended Use:

DART-12 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.

Device Description:

DART-12 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 *DART-12* 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 *DART-12*, bring the leaves to specified positions. The *DART-12* control software operates as a sequential linear process, where the apertures are performed one by one.

To form a desired aperture, *DART-12* Control Software calculates leaves motion from knowledge of their current positions (measured) and desired destination (delivered by treatment plan).

DART-12 displays an image reflecting the leaves current position. Numeric indication of each leaf position is available.

DART-12 three operation modes are: Step-and-Shoot, Dynamic Arc, and dynamic IMRT.

K052705
Page 3 of 3

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

- Dynamic Arc: Irradiating Linac forms an arc while *DART-12* forms apertures at a set of Gantry angles.

- DIMRT: Irradiating Linac is stationary while *DART-12* modifies the apertures.

Substantial Equivalence:

The predicate devices for substantial equivalence are:

1. *AccuLeaf* v2.1 (k040553)
2. BrainLAB MMLC (k020860)

The Dart-12 is substantially equivalent to its predicate devices as the basic features design and intended use are the same or similar. The minor differences in design dimensions and features between the Dart-12 and its predicate devices raise no issues of safety and efficacy as these differences have no effect on the performance, function or intended use of DART-12.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1 2006

Ms. Larisa Gershtein
Quality Assurance Manager
Direx Systems Corp.
437 Turnpike Street
CANTON MA 02021

Re: K052705
Trade/Device Name: *DART-12*
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 18, 2006
Received: January 20, 2006

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.

Attachment **4-1**

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K052705

Device Name:

DART-12

Indications for Use:

DART-12 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.

DART-12 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.

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

510(k) Number _____

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052705

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