510(K) SUMMARY

AccuSoft, AccuSoft XL

OCT - 5 2006

510(k) Number k 062032

Applicant's Name:

Direx Systems Corp.
437 Turnpike Street
Canton, MA 02021
United States of America

Contact Person:

Larisa Gershtein
Direx Systems Corp.
437 Turnpike Street
Canton, MA 02021
Tel: (339) 502 6013
Fax: (339) 502 6018
E-mail: lgershtein@direxusa.com

Trade Name:

AccuSoft, AccuSoft-XL

Model:

AccuSoft-XL

Common Name:

Radiation Treatment Planning System

Classification Name:

System, Planning, Radiation Therapy Treatment

Classification:

The FDA has classified this type of devices as class II (product code 90 MUJ, Regulation No. 892.5050), review by the Radiology Panel.

Predicate Devices:

- The Company's *AccuSoft* v3.14 (K040474)
- PerMedics' *Odyssey* (K042861)

Performance Standards:

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

However, *AccuSoft-XL* complies with the following voluntary standards:

- Guidance for FDA Reviewers and Industry – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; May 11, 2005.
- IEC 60601-1-4 - Consol. Ed. 1.1 Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems (1996) + A1 (1999).
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices; September 9, 1999.

Intended Use:

AccuSoft-XL is to be used for the computation, display, evaluation and output of radiation dose estimations to be submitted for independent clinical review and judgment prior to use in radiation therapy.

Device Description:

AccuSoft-XL is a radiation treatment planning system (RTPS), consisting of a collection of software modules that execute algorithms to produce estimates of beam radiation dose distribution in body tissues. It includes the image, delineation and beam planning techniques.

AccuSoft-XL is an upgraded version of the Company's proprietary AccuSoft v3.14. It is designed to operate with Cones, Blocks and Wedges, as well as with a Micro-Multi-Leaf Collimator (MMLC), such that the shape of the radiation beam conforms to the irregular shape of the lesion. The ability to shape the radiation beam enables maximization of the radiation dose to the lesion, while minimizing the radiation dose to the surrounding normal tissue and critical structures.

AccuSoft-XL is used for computation, display, evaluation, and output of dose estimations, including those for several modes of treatment, such as Conformal, Blocks and Wedges, Cones and Intensity Modulated Radiation Therapy (IMRT). There are several IMRT treatment modes: (1) Intensity Modulated Arc Therapy (IMAT) – in which an irradiating Linac rotates while leaves form a sequence of apertures (arcs), (2) Dynamic Intensity Modulated Radiation Therapy (DIMRT) – in which irradiating Linac is stationary while leaves form a sequence of apertures, as well as (3) Intensity Modulated Radiation Therapy (also called Step-and-Shoot), during which apertures are formed prior to irradiation

The Linac and Cones / MMLC configuration parameters shall be written to a file to be sent to both the Linac and the Company's proprietary Cone Changer / MMLC devices.

In the *AccuFusion* module, *AccuSoft-XL* combines two different types of axial images. This enables to enhance the display of various materials or tissues and to perform target delineation on fused images. Thus, CT images and Secondary Images (CT, MRI, PET, etc.) in DICOM format from the same patient can be combined, resulting in an improved single image.

Substantial Equivalence:

AccuSoft-XL is essentially similar to AccuSoft v3.14 predicate device. It incorporates additional features, such as Fusion of axial images, Treatment Plan for Blocks and Wedges, and Cones, featured in the predicate device *Odyssey*.

Based on validations and performance testing results, Direx Systems Corp. believes that *AccuSoft-XL* is substantially equivalent to the above predicate devices without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT - 5 2006

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

Re: K062032
Trade/Device Name: AccuSoft-XL
Regulation Number: 21 CFR §892.5050j
Regulation Name: Medical charge-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: September 11, 2006
Received: September 12, 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
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 STATEMENT

510(k) Number (if known): K062032

Device Name:

AccuSoft-XL

Indications for Use:

AccuSoft-XL is to be used for the computation, display, evaluation and output of radiation dose estimations to be submitted for independent clinical review and judgment prior to use in radiation therapy.

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

David G. Hoyson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062032

Prescription Use ✓