JUN 2 3 2004

510(K) SUMMARY

AccuSoft

510(k) Number K 040474

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, MA 01760
Tel: (888) 874 7837
Fax: (508) 651-8125
E-mail: lgershtein@direxusa.com

Trade Name:

AccuSoft

Model:

AccuSoft

Classification Name:

System, Planning, Radiation Therapy Treatment

Classification:

The FDA has classified this type of devices as class II (product code 90 IYE, Regulation No. 892.5050); they are reviewed by the Radiology Panel.

Applicable Standards:

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

However, *AccuSoft* complies with the following consensus standards:

- IEC 60812 (1985) - Failure Mode and Effects Analysis.
- IEC 60601-1-4 – Consol. Ed. 1.1 (2000-04) Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems.
- IEEE Std 829 (1998) Standard for Software Test Documentation
- IEEE Std 830 (1998) Recommended Practice for Software Requirements Specifications
- ISO 14971 (2000) Medical devices – Application of risk management to medical devices
- Guidance on Medical Device Patient Labeling; Final Guidance for Industry and

FDA Reviewers, April 19, 2001

- An Introduction to Human Factors in Medical Devices, December 1996
- Guidance for FDA Reviewers and Industry, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices May 29, 1998
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff January 11, 2002
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices September 9, 1999

Intended Use:

AccuSoft is intended to be used for the computation, display, evaluation, and output documentation of radiation dose estimations **including those for Intensity Modulated Radiation Treatment (IMRT)** that are to be submitted for independent clinical review and verification by a physicist or physician prior to use.

The application provides output data in the form of displays or hardcopy printouts to guide a physician in selecting the optimum patient treatment plan. It is intended to provide a report to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist or dosimetrist.

Device Description:

AccuSoft is a radiation treatment planning system. It consists of a software package that executes accepted algorithmic approaches to produce radiation dose estimations and of extensive verification and quality assurance (QA) procedures to enable the proper system and patient setup and adequate radiation delivery.

It includes the image, delineation and beam planning techniques. The ability to shape the radiation beam enables the user to treat irregularly shaped lesions, maximizing the radiation dose to the lesion, while minimizing the radiation dose to the surrounding normal tissue and critical structures.

Predicate Devices:

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

- AccuSoft, v2.02., radiation treatment planning system cleared on December 15, 2003 (Tracking number K032171), manufacturer *Direx Systems Corp.*
- DMLC IV – ERGO cleared on October 23, 2000 (Tracking number K001163). Manufacturer *3D Line*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2004

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

Re: K040474
Trade/Device Name: AccuSoft
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: May 18, 2004
Received: May 21, 2004

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 (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): k040474

Device Name:

AccuSoft

Indications for Use:

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

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040474