SECTION 3 510(K) SUMMARY

DEC - 7 2010

Pronex

510(K) number K102765

Date Prepared	September 2010
Applicant's Name	Direx Systems Corporation 437 Turnpike Street Canton, MA 02021 Tel:(339) 502-6013 Fax:(339) 502-6018
Contact Person:	Ms. Larisa Gershtein e-mail:lgershtein@direxusa.com
Trade Name	**Pronex**
Classification Name	Medical Charged –Particle Radiation Therapy System
Classification	The FDA has classified this type of devices as class II (Product code IYE,21 CFR. 892.5050). Radiology Panel reviews this type of device.
Predicate Devices	ClearVue prone Breast Treatment Table, K090349, Prone Breast Positioning Board, Model 37-018, K971382
Establishment Registration Number	1224828
Intended use	Positioning a patient for prone breast radiation therapy.
Device Description	The device comprise two rigid mechanical structures, each incorporating: * A tabletop for supporting a patient's torso in the prone

position such that a treated breast is able to hang down through a tabletop opening. The tabletops for each structure are identical.

* A selection of two application-oriented supporting structures. Each supporting structure is composed of a base for interfacing the device to a couch, and spacers that connect the tabletop to the base such that a space is provided for a treated breast. The applications are imaging and radiation treatment.

The imaging-oriented supporting structure is CT-radiation transparent and is compatible with a 70cm bore and with a CT couch. The treatment-oriented supporting structure is treatment-radiation transparent and is compatible with the treatment couch. The supporting structures do not affect the patient's torso positioning on the tabletop, so as to allow imaging and treatment in the same position.

Substantial Equivalence

The respective couches provide positioning motion. The intended use, functionality, technological characteristics and materials of **the device** are similar to those of the predicate devices. Analysis of similarities and differences led Direx Systems Corp. to conclude that **the device** is substantially equivalent to its predicate devices without raising new safety and/or effectiveness issues

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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

DEC - 7 2010

Re: K102765
Trade/Device Name: Pronex
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 15, 2010
Received: September 24, 2010

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

DiREX
SYSTEMS CORP.

SECTION 2 INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known): K102765

DEC - 7 2010

Device Name: Pronex

Indications for Use:

Pronex is used to position a patient for prone breast radiation therapy.

Prescription Use - Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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