DEC 2 3 2003

APPENDIX 6: 510 (K) SUMMARY K03/281

510(k) Summary
As required by 807.92
For ERGO SRS
Prepared on January 17, 2003

Submitted by: 3D Line USA, Inc.
11419 Cronridge Dr. Suite 15
Owings Mills, MD 21117

Tel. 410-581-6701 Fax: 410-581-9007

Contact Person: Nader Salehi
Vice President

Device Trade Name: **ERGO SRS**

Common Name: Stereotactic radiosurgery treatment planning module

Classification: Medical charged-particle radiation therapy system, Class II
Sec. 21 CFR 892.5050

Predicate Device: **PLATO SRS V2,** K010784

Manufactured by: Nucletron Corporation, 7080 Columbia Gateway Drive, Columbia, MD 21046-2133

Description of the Device: **ERGO SRS** is a stereotactic radiosurgery treatment planning software module for 3D Line USA's **ERGO** radiotherapy treatment planning system (K001163).

Intended Use for the Device: It is intended for use in the planning of 3 dimensional radiation therapy.

Substantial Equivalence to Predicate Device: **ERGO SRS** is identical to **PLATO SRS V2**. It is the same software integrated with 3D Line USA's **ERGO** system rather than Nucletron's **PLATO** system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

Mr. Nader Salehi
Vice President
3D Line USA, Inc.
Reston Executive Center
12100 Sunset Hills Road, Suite 150
RESTON VA 20190

Re: K031281
Trade/Device Name: ERGO SRS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charge-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: December 4, 2003
Received: December 8, 2003

Dear Mr. Salehi:

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

Applicant: _3D Line USA, Inc._____

510(k) Number (if known): ___K031281_____

Device Name: __**ERGO SRS**_____

Indications For Use:

ERGO SRS is stereotactic radiosurgery module for **DMLCIV-ERGO** (K001163). It is an accessory to linear accelerators used for radiation therapy. It is indicated for use in the planning of 3 dimensional radiation therapy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031281

3D Line USA, Inc.
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