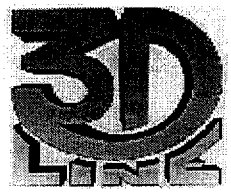
Premarket Notification
3D Line: EVTOOL
Date : 20 October 2001

K013535

JAN 18 2002



3D Line USA
2807 Old Court Rd
Baltimore MD 21208
Phone: 410-580-1730
Fax: 410-580-1732

Date: October 20, 2001

Department of Health and Human Services
Center of Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

a. Submitter of 510(k)

Company name:	**3D Line USA**
Registration #	9041925
Address:	2807 Old Court Road
	Baltimore, MD 21208
Contact Person:	Karen Rigamonti
	President
Phone:	410-580-1730
Fax:	410-580-1732

b. Device Name:

Trade/Proprietary Name:	EVTOOL
Common/Usual Name:	Radiation Therapy Planning System
Classification Name:	Accelerator, Linear, Medical, Accessory
	21 CFR 892.5050 Class II.

c. Legally Marketed Predicate Device(s)

Our device is substantially equivalent to the legally marketed predicate devices cited in the table below.

Manufacturer	Device	510(k) #
3D Line	DMLC IV-ERGO	K001163

d. Description

EVTOOL is a software module that has been designed to expand the features and functions of the DMLC IV- ERGO treatment planning software. The software runs on a silicon graphics workstation and Irix operating system.

EVTOOL software is used for comparing and evaluating radiation therapy treatment plans from a quantitative and radiobiological point of view. The software displays one or more stored plans for comparison and analysis. It can display the dose volume histograms of the various plans and organ dose statistics (mean, modal, maximum and minimum dose). It allows the user to input radiobiological corrections in order to enhance the evaluation of the treatment plan. It also optimizes the dose prescription by displaying reference dose and number of treatment fractions.

EVTOOL is fully integrated into the ERGO treatment planning environment in order to easily exchange information from the patients' database. The patient information is selected and automatically loaded into the EVTOOL software. From the patient database the user can select one or multiple treatment plans to display and calculate the dose statistics, including dose volume histograms and radiobiological models. The analytical information is displayed in 4 windows with a zoom capability. These windows can display the overall plan and individual organs of interest. EVTOOL provides options for incorporating radiobiological corrections to assist the physician in determining the optimal dose prescription and fractionation based on TCP (Tumor Control Probability), NTCP (Normal Tissue Complication Probability) and UTCP (Uncomplicated Tumor Control Probability) values.

This software is a useful tool in evaluating the entire volumetric treatment plan, it is not used to directly treat the patient. It provides the physician with a tool to compare various plan versions side by side in order to determine the most appropriate treatment plan to be used with the DMLC IV equipment. The display of the treatment plans within EVTOOL provides a permanent record and effective control on the actual dose delivered to the patient.

e. Intended use

EVTOOL software module provides the ability to compare and evaluate the radiation dose delivery to the tumor volume and surrounding organs from generated dose volume histograms and radiobiological values. It expands the DMLC IV-ERGO system, which is a combination of a radiation collimator with multiple tungsten leaves that move during delivery of radiation therapy and a computer based treatment planning and control system.

f. Summary of technological considerations

The EVTOOL software is substantially equivalent to the predicate devices. It enhances the functionality of the defined predicate device to provide evaluation tools for radiation therapy treatment planning.

Karen Rigamonti — 10/18/01

Name: Karen Rigamonti, MD, MBA, M.P.H. Date
Title President
3D Line USA, Inc.
Baltimore, MD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

Karen Rigamonti, M.D.
President
3D Line USA, Inc.
2807 Old Court Road
BALTIMORE MD 21208

Re: K013535
Trade/Device Name: EVTOOL Model V 1.0
Accessory to RTP System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: October 20, 2001
Received: October 23, 2001

Dear Dr. Rigamonti:

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 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 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:

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" (21 CFR Part 807.97). 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

Premarket Notification
3D Line: EVTOOL
Date : 20 October 2001

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Statement of Intended Use

Device Name: EVTOOL

Intended use

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Prescription use

The EVTOOL is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

Karen Rigamonti — 10/18/01

Name: Karen Rigamonti, MD, MBA, M.P.H. — Date
Title: President
3D Line USA, Inc.
Baltimore, MD

Prescription Use ✓

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013535