DEC - 7 1999

K 991706

VIRTUOSO
Summary of Safety and Effectiveness

Device Name:

Classification Name:	Instrument, Stereotaxic: 21 CFR 882.4560, Class II
Common/Usual Name:	Stereotaxic Planning Software
Proprietary Name:	VIRTUOSO – Stereotaxic Planning Software

Device Sponsor:

Manufacturer:	Stryker Corporation Stryker Leibinger GmbH and Co. KG Botzinger Straβe 41 D-79111 Freiburg Germany Registration No.: 8010177
Distributor:	Stryker Corporation Stryker Leibinger 4100 E. Milham Avenue Kalamazoo, MI 49001 Registration No.: 1811755

Regulatory Class: Class II

Summary of Safety and Effectiveness:

The VIRTUOSO Stereotaxic Planning Software is a software-based planning system intended for the creation of treatment plans for radiation therapy with high-energetic phontons. It is used for patients which are selected for a precise radiation therapeutical treatment according to medical diagnosis. It may be used only by radiation therapeutical experts under medical supervision in rooms which are suitable for the operation of computers.

The VIRTUOSO Stereotaxic Planning Software is equivalent to the STP treatment planning software K892425D. The VIRTUOSO Stereotaxic Planning Software does not raise any new safety and efficacy concerns when compared to this similar legally marketed software. Therefore, the VIRTUOSO Stereotaxic Planning Software is substantially equivalent to this existing software.

By: Nicole Petty

Nicole Petty
Regulatory Affairs Representative
Stryker Instruments

Dated: 5-18-99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 1999

Ms. Nicole Petty
Regulatory Affairs Analyst
Stryker Corporation
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K991706
Trade Name: VIRTUOSO Stereotactic Planning Software
Regulatory Class: II
Product Code: HAW
Dated: September 20, 1999
Received: September 21, 1999

Dear Ms. Petty:

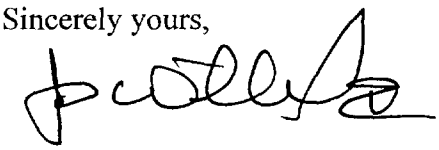
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K 991706

Device Name VIRTUOSO – Stereotaxic Planning Software

Indications VIRTUOSO is a software-based planning system used to create treatment plans for radiation therapy with high-energetic phontons. It is used for patients which are selected for a precise radiation therapeutical treatment according to medical diagnosis. It may be used only by radiation therapeutical experts under medical supervision in rooms which are suitable for the operation of computers.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991706