AMERICAN RADIOSURGERY

510(k) Summary

NOV - 5 2010

510(k)	K101220
Submitter/Applicant Name:	American Radiosurgery, Inc.
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Contact person:	Dan Olivier (CCS, Inc.)
Phone number:	(858) 675-8200
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Date prepared:	October 30, 2010
Trade name:	Explorer 4D™ Treatment Planning System
Common name:	Radiation Therapy Treatment Planning System
Classification name:	System, Planning, Radiation Therapy Treatment
Classification:	21 CFR Part 892.5050 Class II

Substantial equivalence claimed to:
This submission for the Explorer 4D™ Treatment Planning System is functionally and substantially equivalent to the K093588 Explorer 4D™ Treatment Planning System with the addition of the ability to import MR as well as CT images. Both systems share the same user interface and dose calculation algorithms; the only difference is the ability to import both CT and MR images.

Description
The Explorer 4D™ Treatment Planning System (TPS) provides individual treatment plans for patients undergoing gamma radiation therapy treatment. The TPS provides for the import of patient images and selecting a series of relevant patient images to create a treatment plan.

Precise calculation of the dose delivery parameters is supported by the registration of fiducial markers as a reference point between patient images. These images are then annotated with the region of interest (ROI) to be exposed to radiation. Several tools are provided to adjust the ROI based on the desired treatment area, within these regions "shots" (radiation sources) and associated treatment dose levels are defined as they related to a specified collimator size.

When the plan definition is completed the operator can save or export the treatment plan.

Intended Use

The Explorer 4D™ Treatment Planning System software is intended for use in preparing treatment plans for patients who have intracranial diseases where neurological radio surgery has been prescribed.

The software is used to electronically import CT and MR images to determine the precise location of the target, to define and visualize treatment beam locations, and to visualize dose to the target and other structures.

Substantial Equivalence

Version 2.1 of the Explorer 4D™ Treatment Planning System include the capability to prepare treatment plans using MR images as well as CT images cleared under submission K093588 (version 2.0). Functional testing has demonstrated that version 2.1 is safe and effective and accuracy comparison tests have demonstrated equivalent performance using MR images as obtained using CT images.

Equivalence Comparison		
Item	**Device**	**Predicate**
Name	Explorer 4DTM Treatment Planning System version 2.1 (K101220)	Explorer 4DTM Treatment Planning System version 2.0 (K093588)
Indications for Use	The Explorer 4D™ Treatment Planning System software is intended for use in preparing treatment plans for patients who have intracranial diseases where neurological radio surgery has been prescribed. The software is used to electronically import CT and MR images to determine the precise location of the target, to define and visualize treatment beam locations, and to visualize dose to the target and other structures.	The Explorer 4D™ Treatment Planning System software is intended for use in preparing treatment plans for patients who have intracranial diseases where neurological radio surgery has been prescribed. The software is used to electronically import CT images to determine the precise location of the target, to define and visualize treatment beam locations, and to visualize dose to the target and other structures.
System Functions	The Explorer 4D™ Treatment Planning System (TPS) imports patient images to determine the precise location of the target for gamma irradiation.	The Explorer 4D™ Treatment Planning System (TPS) imports patient images to determine the precise location of the target for gamma irradiation.
Technological characteristics	Technological characteristics include 3D imaging of treatment beam locations to visualize target dose overlaid on CT and MR images.	Technological characteristics include 3D imaging of treatment beam locations to visualize target dose overlaid on CT images.
Import data	CT and MR images	CT

Equivalence Comparison		
Item	**Device**	**Predicate**
Data interfaces	TCP/IP network interface	TCP/IP network interface
User access	Secured through identification code and password	Secured through identification code and password
Safety Features	Requires physician approval of treatment plans	Requires physician approval of treatment plans
Non-clinical testing	Testing includes functional coverage of all requirements and accuracy comparison tests using CT and MR images	Testing includes functional coverage of all requirements
Test results	Test results have been verified by physicist manual calculations as accurate for CT and MR images	Test results have been verified by physicist manual calculations as accurate for CT images
Software version	2.1	2.0

Performance Data

Testing for the Explorer 4D™ Treatment Planning System is the same as was performed for the predicate device (K093588 Explorer 4D™ Treatment Planning System) with the difference that all tests were conducted with the software version 2.1 using MR images instead of CT images. In addition, separate accuracy comparison tests were also conducted showing the results using MR images are equivalent to the results generated using CT images.

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

American Radiosurgery, Inc.
c/o Mr. Dan Olivier
President
Certified Compliance Solutions, Inc.
11665 Avena Place, Suite 203
SAN DIEGO CA 92128

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Re: K101220
Trade Name: Explorer 4D™ Treatment Planning System
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: October 24, 2010
Received: October 25, 2010

Dear Mr Oliver:

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

K101220

4. Indications for Use

510(k) Number: K101220
Device Name: Explorer 4D™ Treatment Planning System

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Indications for Use:

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Prescription Use ___X_____ (Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

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

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