DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 11, 2015

Siris Medical
% Ms. Cynthia Pillar
Consultant
CJP Consulting, Inc.
5831 N Kostner Avenue
CHICAGO IL 60646

Re: K151560
Trade/Device Name: QuickPlan
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: June 29, 2015
Received: July 1, 2015

Dear Ms. Pillar:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151560

Device Name
QuickPlan

Indications for Use *(Describe)*
The QuickPlan Treatment Planning System is indicated for use in planning radiotherapy treatments for patients with malignant or benign diseases. After image acquisition, QuickPlan supports the treatment planning process for external beam irradiation with photon, electron, and proton beams by predicting a plan.

The QuickPlan software does not provide full plan generation; it does not include final dose calculation, final beam geometry, nor does it enable plan approval. QuickPlan is not connected to any radiation emitting equipment. The QuickPlan software is intended for use by trained medical professionals to use in clinical settings. The QuickPlan software is compatible with Treatment Planning Systems that use the DICOM-RT format.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Phone +1 650 394 5161
Fax +1 650 434 3970
257 Castro Street, Ste 224, Mountain View, CA 94041

SECTION 5: TRADITIONAL 510(k) SUMMARY AS REQUIRED BY 21 CFR 807.92

Traditional 510(k) Summary

Date Prepared: June 29, 2015

Submitter:
SIRIS MEDICAL
257 Castro Street, Suite 224
Mountain View, CA 94041
Telephone: 1 (650) 394-5161

Contact:
Cynthia J. Pillar, RAC
Phone: 1 (773) 677-8886

Trade/Proprietary Name of Device: QUICKPLAN (K151560)

Common Name of Device: Medical charged-particle radiation therapy system

Classification: Class II per 21 CFR 892.5050, System, Planning, Radiation Therapy Treatment, Product Code MUJ

Legally Marketed Predicate Device: Eclipse Treatment Planning System manufactured by Varian Medical Systems Inc., K141283, Class II per 21 CFR 892.5050, Medical charged-particle radiation therapy system, Product Code MUJ

Description of New QUICKPLAN Device:

The new QUICKPLAN Software manufactured by Siris Medical is an independent software solution to plan radiotherapy treatments for patients with malignant or benign diseases. It is used to plan external beam irradiation with photon, electron, and proton beams. The new QUICKPLAN Software is intended for trained medical professionals to use in clinical settings. The new QUICKPLAN software application includes three modules:

- QuickMatch – Matches a critical structure-set to the closest match within a database. It is a rapid file locator.
- QuickPredict – Predicts the dose to critical structures based upon models extracted from historical data looking through previous patient data.

Phone +1 650 394 5161
Fax +1 650 434 3970
257 Castro Street, Ste 224, Mountain View, CA 94041

- QuickCompare – Provides dose estimates to critical structures with one or more alternative energy modalities, i.e. Photon vs. Proton.

The new QuickPlan software does not provide full plan generation; it does not include final dose calculation, final beam geometry, nor does it enable plan approval.

As with the RapidPlan module of the predicate Eclipse Treatment Planning System by Varian Medical Systems, Inc. (K141283), the new QUICKPLAN software uses GHz microprocessor technology along with clinician guided learning and standardized structured data sets to yield knowledge-based planning. Specifically, knowledge-based planning is the result of using dose and anatomical information from previously treated patients to realize models that can accurately estimate deliverable treatment plans based on the type of external radiation source being utilized.

Historically, radiation treatment planning required a team of specialists working with planning software to deliver a prescribed dose of treatment to the tumor while minimizing the dose to surrounding organs referred to as ‘organs at risk’, or OARs. Coordination of the team of specialists resulted in a treatment planning process that typically spanned several hours over several days.

The treatment planning process typically involves the following steps:

1. Import of patient images
2. Creation of critical structures and tumor volumes
3. Definition of the 3D volume of the tumor
4. Definition of the 3D volume of the Organs at Risk
5. Establishment an estimate of the dose that is desired to the tumor
6. Establishment of a maximum threshold for the dose to each of the OARs
7. Generation of a plan beam geometry
8. Dose calculation
9. Plan approval
10. Quality Assurance activities

As with the predicate software, the new QuickPlan software involves the following steps:

1. Definition of the 3D volume of the tumor
2. Definition of the 3D volume of the OARs
3. Establishment an estimate of the dose that is desired to the tumor
4. Establishment of a maximum threshold for the dose to each of the OARs

Phone +1 650 394 5161
Fax +1 650 434 3970
257 Castro Street, Ste 224, Mountain View, CA 94041

Once these steps have been completed, a software program solves for the 4D positioning of the radiation beam for these constraints. This process can take anywhere from 20 – 40 minutes each iteration. If the specialists decide to change the target delivery volume by a few millimeters to determine the effect on the dose to the tumor and OARs, the treatment planning process must begin again.

The new QUICKPLAN software will enable the physician to see the implications of changing these treatment parameters without needing to involve the whole team. In addition, the new QUICKPLAN software eliminates the need to run the treatment planning optimizer again until the clinician is satisfied with the dose distribution. The new QUICKPLAN includes a manual contour editor that allows the clinician to augment or redact margins as they see fit, and provides near-instantaneous insight as to how changes affect dose to critical structures, saving valuable time to treatment.

It is important to note that the new QUICKPLAN software is intended as a tool for the clinician to use in planning radiotherapy treatments for patients. It is not connected to, nor does it control, any other devices. The new QUICKPLAN software does not deliver any energy or treatment to the patient. The new QuickPlan software also does not provide full plan generation; it does not include final dose calculation, final beam geometry, nor does it enable plan approval.

Indications for Use of the New QUICKPLAN Device:

The QuickPlan Treatment Planning System is indicated for use in planning radiotherapy treatments for patients with malignant or benign diseases. After image acquisition, QuickPlan supports the treatment planning process for external beam irradiation with photon, electron, and proton beams by predicting a plan.

The QuickPlan software does not provide full plan generation; it does not include final dose calculation, final beam geometry, nor does it enable plan approval. QuickPlan is not connected to any radiation emitting equipment. The QuickPlan Software is intended for use by trained medical professionals to use in clinical settings. The QuickPlan software is compatible with Treatment Planning Systems that use the DICOM-RT format.

Intended Use of the New QUICKPLAN Device

The QuickPlan Treatment Planning System is intended for use in planning radiotherapy treatments for patients with malignant or benign diseases.

After image acquisition, QuickPlan supports the treatment planning process for

Phone +1 650 394 5161
Fax +1 650 434 3970
257 Castro Street, Ste 224, Mountain View, CA 94041

external beam irradiation with photon, electron, and proton beams by predicting a plan.

The intended use of the new QUICKPLAN device and the predicate Eclipse RapidPlan module device are the same. Both devices are intended to plan radiotherapy treatments for patients with malignant or benign diseases. The new QUICKPLAN does not claim to include the additional indications of internal irradiation (brachytherapy) or treatment of neoplasms of the eye that are specifically stated in the predicate Varian Medical Systems - Eclipse (K141283) indications for use statement. This difference is not critical to the intended use of the new QUICKPLAN device for its indications, nor does it affect the safety and effectiveness of the device when used as labeled. In addition, the new QUICKPLAN software device performs only a subset of what a full Treatment Planning System (TPS) does. It functions outside of the full TPS by allowing the user to predict plans using DICOM-RT files imported from the full TPS. The risk to the user or patient is extremely low since the QUICKPLAN software does not control any external treatment delivery equipment. Once the QUICKPLAN treatment plan is predicted, the plan is uploaded into the full TPS for dose calculation, plan approval and quality assurance activities, which is identical to what the TPS-produced plans must go through when used without the new QUICKPLAN software.

Comparison of the Technological Features of the New Device and Predicate Device:

We believe that the new QUICKPLAN device has been shown to be substantially equivalent to the predicate Varian Medical Systems Eclipse Treatment Planning System RapidPlan module (K141283). The new and predicate devices are very similar in overall design and technology, principles of operation, and intended use. Main differences are as follows:

1. The new QUICKPLAN device is not a full treatment planning system (fTPS) and includes only treatment planning prediction, a subset of an fTPS process.

2. The new QUICKPLAN device limits its indications to patients with malignant and benign diseases. It does not include internal irradiation (brachytherapy) or treatment of neoplasms of the eye. It specifically excludes functions that the new QUICKPLAN does not provide to distinguish itself from an fTPS.

Phone +1 650 394 5161
Fax +1 650 434 3970
257 Castro Street, Ste 224, Mountain View, CA 94041

3. The new QUICKPLAN device performs simultaneous dose prediction and contouring. The predicate Eclipse performs these steps of the process separately.

4. The new QUICKPLAN device uses Dose Indices to display predicted doses and the predicate device uses Dose Volume Histograms. .

The differences between the new QUICKPLAN device and the predicate Varian Eclipse Treatment Planning System RapidPlan module device do not raise any new questions of safety or effectiveness. Shown in TABLE 5.1 below are selected properties and characteristics of the new Siris Medical QUICKPLAN software and the predicate Varian Medical Systems Eclipse Treatment Planning System RapidPlan device (K141283) compared side-by-side.

Device Comparison Table 5.1

DESCRIPTIVE INFORMATION	NEW QUICKPLAN SOFTWARE	PREDICATE DEVICE: Varian Eclipse Treatment Planning System RapidPlan module (K141283)
Indications for Use	The QuickPlan Treatment Planning System is indicated for use in planning radiotherapy treatments for patients with malignant or benign diseases. After image acquisition, QuickPlan supports the treatment planning process for external beam irradiation with photon, electron, and proton beams by predicting a plan. The QuickPlan software does not provide full plan generation; it does not include final dose calculation, final beam geometry, nor does it enable plan approval.	The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron, and proton beams, as well as for internal irradiation (brachytherapy) treatments. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye.

Phone +1 650 394 5161
Fax +1 650 434 3970
257 Castro Street, Ste 224, Mountain View, CA 94041

	QuickPlan is not connected to any radiation emitting equipment. The QuickPlan Software is intended for use by trained medical professionals to use in clinical settings. The QuickPlan software is compatible with Treatment Planning Systems that use the DICOM-RT format.	
Intended Use	The QuickPlan Treatment Planning System is intended for use in planning radiotherapy treatments for patients with malignant or benign diseases.	Used to plan radiotherapy treatments for patients with malignant or benign diseases.
Product Code	MUJ	MUJ
Regulation Number	892.5050	892.5050
Regulation Name	Medical charged-particle radiation therapy system	Medical charged-particle radiation therapy system
Intended Users	Medical Professionals	Medical Professionals
Environment of Use	Clinical Setting	Clinical Setting
Display	Computer, Web Browser	Computer, Web Browser
FEATURES	**NEW QUICKPLAN SOFTWARE APPLICATION**	**PREDICATE DEVICE: Varian Eclipse Treatment Planning System RapidPlan module (K141283)**
Full Treatment Planning System	No	Yes
Ability to import DICOM-RT	Yes	Yes
Structure	Yes	Yes

Phone +1 650 394 5161
Fax +1 650 434 3970
257 Castro Street, Ste 224, Mountain View, CA 94041

Identification		
Dose Prediction	Yes	Yes
Contouring	Yes	Yes
Simultaneous Dose Prediction & Contouring	Yes	No
Axial view	Yes	Yes
Zoom functionality	Yes	Yes
Panning functionality	Yes	Yes
Error in patient loading displayed to user	Yes	Yes
Contour display errors displayed to the user	Yes	Yes
Display of dose	Dose Indices	Dose Volume Histograms

TABLE 5.1 – Device Comparison Table

Testing:

Non-Clinical Performance Data Testing:

Performance bench testing was conducted to verify that the new QUICKPLAN software device meets all design specifications and demonstrates substantial equivalence to its predicate, the Eclipse Treatment Planning System Rapid Plan module by Varian Medical Systems, Inc. (K141283). In addition, the new QUICKPLAN software device complies with the following standards:

- IEC 62083 – Edition 2.0 – 2009-09 – Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems
- IEC 62366 – Medical devices – Application of usability engineering to medical devices

Biocompatibility:

Since the new QUICKPLAN software device is stand alone software, there are no patient contacting parts and therefore no biocompatibility testing has been performed.

Phone +1 650 394 5161
Fax +1 650 434 3970
257 Castro Street, Ste 224, Mountain View, CA 94041

Software:

The new QUICKPLAN software has been validated and complies with the FDA Guidance for the content of Premarket Submission for Software Contained in Medical Devices as well as IEC 62304: 2006, Medical device software – Software life cycle processes.

Risk Analysis:

Risk management activities were performed throughout development of the new QUICKPLAN software device. Potential individual risks were identified, evaluated, and mitigated to the extent possible. Remaining overall residual risk was assessed and determined that any remaining risk is as low as possible and is outweighed by the benefits of the new QUICKPLAN software.

Clinical Performance Testing:

No clinical testing has been performed in support of this QUICKPLAN software 510(k) submission.

Conclusion:

The conclusions drawn from the specifications and performance testing of the new QUICKPLAN software device demonstrate that the new QUICKPLAN software device is at least as safe and as effective and performs as well as or better than the predicate the Eclipse Treatment Planning System Rapid Plan module by Varian Medical Systems, Inc. (K141283). For these reasons, we believe the new QUICKPLAN software device is substantially equivalent to the predicate device.