



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

Aurora Technology Development, LLC
% Mr. Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
Po Box 3018
NEDERLAND CO 80466

February 3, 2016

Re: K152994
Trade/Device Name: Adaptivo
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 29, 2015
Received: December 30, 2015

Dear Mr. Kroenke:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a large, faint, light-blue watermark of the letters "FDA".

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

4 Indications for Use

Indications for Use

510(k) Number (if known): K152994

Device Name: Aurora Technology Development, LLC Adaptivo

Indications For Use: Adaptivo is a stand-alone software product that provides comparative dose information about the daily and cumulative dose received by a radiotherapy patient relative to their treatment plan. It is to be used by a radiation oncology licensed medical professional as a guide to provide pre-treatment plan delivery verification; to monitor daily treatments and indicate potential clinically relevant deviations from the intended plan delivery; to provide estimates of daily and cumulative dose delivered to the patient, accounting for patient position and anatomy changes; and to aid in determining whether a patient plan should be altered partway through the course of treatment in order to meet the treatment planning goals. Adaptivo is not a primary treatment planning software, and cannot be used to generate radiotherapy treatment plans.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

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5 510(k) Summary

510(k) Summary
provided in accordance with 21 CFR §807.92(C)

Submission Date: 12 October 2015

Submitter: Aurora Technology Development, LLC
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Madison, WI 53719

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Manufacturing Site: Aurora Technology Development, LLC
555 D’Onofrio Drive, Suite 104
Madison, WI 53719

Trade Name: Aurora Technology Development, LLC Adaptivo

Common Name: Quality Assurance Software for Patient Radiation Treatment

Classification Name: Accelerator, Linear, Medical

Classification Regulation: 21 CFR §892.5050

Product Code: IYE

Substantially Equivalent Devices:

<i>New ATD Model</i>	<i>Predicate 510(k) Number</i>	<i>Predicate Manufacturer / Model</i>
ATD Adaptivo	K141800	Sun Nuclear Corporation Model 1215 PerFRACTION
	K132605	Math Resolutions Dosimetry Check v4.1
	K140660	Mobius Medical Systems Mobius3D

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Device Description:

Aurora Technology Development (ATD) Adaptivo is a stand-alone software product that provides comparative dose information about the daily and cumulative dose received by a radiotherapy patient relative to their treatment plan. It provides:

- pre-treatment plan delivery verification;
- the ability to monitor daily treatments and indicate potential clinically relevant deviations from the intended plan delivery;
- estimates of daily and cumulative dose delivered to the patient, accounting for patient position and anatomy changes; and
- an aid in determining whether a patient plan should be altered partway through the course of treatment in order to meet the treatment planning goals.

ATD Adaptivo is not a primary treatment planning software, and cannot be used to generate radiotherapy treatment plans.

ATD Adaptivo has two (2) primary software modules: (1) the Adaptive Dose Recalculation (ADR) module; and (2) the In-vivo Dosimetry (IVD) module. These two (2) modules integrate seamlessly to provide the user full benefit of ATD Adaptivo.

Intended Use:

Adaptivo is a stand-alone software product that provides comparative dose information about the daily and cumulative dose received by a radiotherapy patient relative to their treatment plan. It is to be used by a radiation oncology licensed medical professional as a guide to provide pre-treatment plan delivery verification; to monitor daily treatments and indicate potential clinically relevant deviations from the intended plan delivery; to provide estimates of daily and cumulative dose delivered to the patient, accounting for patient position and anatomy changes; and to aid in determining whether a patient plan should be altered partway through the course of treatment in order to meet the treatment planning goals. Adaptivo is not a primary treatment planning software, and cannot be used to generate radiotherapy treatment plans.

510(k) Summary
provided in accordance with 21 CFR §807.92(C)

Technology Comparison:

ATD Adaptivo employs the same technological characteristics as the predicate device.

<i>Characteristic</i>	<i>Sun Nuclear PerFraction (K141800)</i>	<i>Math Resolution Dosimetry Check (K132605)</i>	<i>Mobius Medical Systems Mobius3D plus FX (K140660)</i>	<i>ATD Adaptivo</i>
<i>Patient data input</i>	Automatic	Manual	Manual	Manual or automatic retrieval from ARIA system
<i>Workflow once patient data are received</i>	Automatic	Manual	Automatic	Automatic
<i>Pre-treatment patient specific QA</i>	Yes	Yes	Yes	Yes
<i>During-treatment delivery monitoring</i>	Yes	No	Yes	Yes
<i>Patient setup error detection</i>	Yes	Yes	No	Yes
<i>Interactive view of dose distribution on complete CT image set</i>	No	Yes	Yes	Yes
<i>Comparison between plan and daily dose</i>	Partial (plan CT only)	No	Partial (plan CT only)	Yes
<i>Comparison between plan and cumulative dose</i>	No	No	No	Yes

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Summary of Performance Testing:

Software

ATD Adaptivo contains MODERATE level of concern software. Software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02;*
- *FDA guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 02 Oct 14; and*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*

Test results indicated that ATD Adaptivo complies with predetermined specifications and the applicable standard.

Performance Testing – Bench

ATD Adaptivo was tested in accordance with internal specifications.

Test results indicated that ATD Adaptivo complies with predetermined specifications.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of ATD Adaptivo. The results of these activities demonstrate that ATD Adaptivo is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, ATD Adaptivo is considered substantially equivalent to the predicate device.