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

Mobius Medical Systems, LP
Stan Eshelman
Chief Operating Officer
5012 Tamarisk St.
BELLAIRE TX 77401-2826

August 27, 2014

Re: K141230
Trade/Device Name: DoseLab Pro
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 24, 2014
Received: July 25, 2014

Dear Mr. Eshelman:

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

Janine Morris
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 on last page.

510(k) Number *(if known)*
K141230

Device Name

DoseLab Pro

Indications for Use *(Describe)*

DoseLab Pro is quality assurance software intended to be used as part of a dosimetry verification system for linear accelerators. It can be used to import radiation-exposed images from scanned film, other measurement devices, and treatment planning systems to display differences between measured and calculated dose distributions.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

5 510(K) SUMMARY

5.1 510(K) OWNER

Mobius Medical Systems, LP
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Bellaire, TX 77401
Tel: (888) 263-8541
Fax: (888) 263-8541

5.2 CONTACT PERSON

Stan Eshelman

5.3 PREPARATION DATE

May 12, 2014

5.4 TRADE NAME

DoseLab Pro

5.5 COMMON NAME

Dosimetry QA Software

5.6 CLASSIFICATION NAME

Accelerator, Linear, Medical
21 CFR 892.5050
Product Code - IYE

5.7 PREDICATE DEVICES

- K935928 RIT 113 (Radiological Imaging Technology, Inc)

5.8 DEVICE DESCRIPTION

DoseLab Pro is a software-only device that uses image analysis to perform radiation oncology quality assurance (QA) as part of a dosimetry verification system. Images are useful in radiation oncology QA because they can be analyzed qualitatively by viewing them and quantitatively using mathematical routines on the data that composes them. A variety of data sets can be analyzed as images in DoseLab Pro. They include radiation dose distributions calculated by treatment planning systems, measured dose distributions from arrays (diode and ion chamber), and radiation-exposed film images.

DoseLab Pro uses numerous built-in image analysis routines that have been developed to perform the tests and meet the standards of the medical physics QA community. In particular, these tools were designed to specifically support completing dose

comparisons. Dose comparisons are made between two, two-dimensional images containing radiation dose and spatial information. The first image is exported from the dose calculation of a patient-specific computed treatment plan from treatment planning software, while the second image is the measured dose from delivery of that plan captured by film or a measurement array. DoseLab Pro assists in aligning the images spatially before performing several different comparisons including Gamma analysis and normalization. DoseLab Pro additionally contains tools for image editing, film image import, and film calibration.

It is important to note that while DoseLab Pro operates in the field of radiation therapy, it is neither a radiation delivery device (e.g. a linear accelerator), nor is it a treatment planning system (TPS). DoseLab Pro is an analysis tool meant solely for quality assurance (QA) purposes when used by trained medical professionals. Being a software-only QA tool, DoseLab Pro never comes into contact with patients.

5.9 Intended Use

DoseLab Pro is quality assurance software intended to be used as part of a dosimetry verification system for linear accelerators. It can be used to import radiation-exposed images from scanned film, other measurement devices, and treatment planning systems to display differences between measured and calculated dose distributions.

5.10 Technological Characteristics Summary

The principle technological characteristic of DoseLab and its predicate device is to perform quality assurance comparisons between images exported from a radiation treatment planning system (TPS) and images from measurements taken during delivery by the radiation delivery system (e.g. linear accelerator). Detailed technological characteristics and indications for use presented within the full set of submitted documentation for this 510(k) application support the claim that DoseLab Pro is substantially equivalent to the predicate device.

5.11 Non-Clinical Performance Data

Non-clinical performance testing was performed on DoseLab Pro as part of its validation. The software Test Plan, Testing Final Report, and Validation Test Records are all submitted as separate appendices to this 510(k) application. Testing involved the use of known good data for inputs into DoseLab Pro and execution of tests designed to confirm expected behavior and expected output. Validation testing was performed manually on the fully compiled software in conditions comparable to its intended clinical environment. All tests passed without defect.

5.12 Conclusions

As a result of the testing done and the comparisons made between technological characteristics, we conclude DoseLab Pro is substantially equivalent to the predicate device.