Deepvoxel, Inc.
% Albert Rego, Ph.D.
Consultant
Albert Rego, Ph.D., Inc.
27001 La Paz Road, Suite #314
MISSION VIEJO CA 92691

April 2, 2021

Re: K202928
Trade/Device Name: DV.Target
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QKB
Dated: February 19, 2021
Received: March 2, 2021

Dear Dr. Rego:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202928

Device Name
DV.Target

Indications for Use *(Describe)*
DV.Target is a software application that enables the routing of DICOM-compliant data (CT Images) to automatic image processing workflows, using machine learning-based algorithms to automatically delineate organs-at-risk (OARs). Contours generated by DV.Target may be used as an input to clinical workflows for treatment planning in radiation therapy.

DV.Target is intended to be used by trained medical professionals including radiologists, radiation oncologists, dosimetrists, and physicists.

DV.Target does not provide a user interface for data visualization. Image data uploaded, auto-contouring results, and other functionalities are managed via an administration interface. Thus, it is required that DV.Target be used in conjunction with appropriate software, such as a treatment planning system (TPS), to review, edit, and approve for all contours generated by DV.Target.

DV.Target is only intended for normal organ contouring, not for tumor or clinical target volume contouring.

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.

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510(k) Summary of Safety and Effectiveness

The assigned 510(k) Number: K202928

1. Submitter

Applicant Information:	DeepVoxel Inc. 22 Talisman Irvine, CA 92620
Phone:	858-281-8029
Email:	support@deep-voxel.com
Contact Person:	Dr. Albert Rego 27001 La Paz Road, Suite #314 Mission Viejo, CA, 92691, USA
Date Prepared:	April 1, 2021

2. Device Name

Trade Name:	DV.Target
Device Common Name:	Radiological Image Processing Software For Radiation Therapy
Regulation Number:	21 CFR 892.2050
Product Code:	QKB
Classification Name:	Picture archiving and communications system
Regulation Class:	Class II

DEEP VOXEL

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3. Identification of Predicate Device

Predicate Device

Table 1. *Identification of Predicate Device.*

Device trade name	510(k) number	Date of clearance	Classification name	Product code	Regulation	Class	Classification panel	Submitter's name
Workflow BoxTM (including DLCExpert™, Embrace:CT™, Embrace:MR™, Re:Contour™)	K181572	July 10, 2018	Picture Archiving and Communications System	LLZ	21CFR 892.2050	Class II	Radiology	Mirada Medical Ltd

Reference Device

MIM – MRT Dosimetry, K182624

4. Indications for use

DV.Target is a software application that enables the routing of DICOM-compliant data (CT Images) to automatic image processing workflows, using machine learning-based algorithms to automatically delineate organs-at-risk (OARs). Contours generated by DV.Target may be used as an input to clinical workflows for treatment planning in radiation therapy.

DV.Target is intended to be used by trained medical professionals including radiologists, radiation oncologists, dosimetrists, and physicists.

DV.Target does not provide a user interface for data visualization. Image data uploaded, auto-contouring results, and other functionalities are managed via an administration interface. Thus, it is required that DV.Target be used in conjunction with appropriate software, such as a treatment planning system (TPS), to review, edit, and approve for all contours generated by DV.Target.

DV.Target is only intended for normal organ contouring, not for tumor or clinical target volume contouring.

5. Device Description

The proposed device, DV.Target, is a standalone software that is designed to be used by trained medical professionals to automatically delineate organs-at-risk (OARs) on CT images. This OARs delineation function, often referred as auto-contouring, is intended to facilitate radiation therapy workflows. Supported image modalities include CT and RTSTURCT.

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DV.Target can automatically delineate major OARs in three anatomical sites --- Head & Neck, Thorax, and Abdomen & Pelvis. It receives CT images in DICOM format as input and automatically generates the contours of OARs, which are stored in DICOM format and in RTSTRUCT modality.

The deployment environment of the proposed device is recommended to be a local network with an existing hospital-grade IT system in place. DV.Target should be installed on a specialized server supporting deep learning processing. After installation, users can login to the DV.Target administration interface via browsers from their local computers. All activities, including auto-contouring, are operated by users through the administration interface.

In addition to auto-contouring, DV.Target also has the following auxiliary functions:

- User interface for receiving, updating and transmitting medical images in DICOM format;
- User management;
- Processed image management and output (RTSTRUCT) file management.

Once data is routed to DV.Target auto-contouring workflows, no user interaction is required, nor provided. The image data, auto-contouring results, and other functionalities can be managed by DV.Target users via an administration user interface. Third-party image visualization and editing software, such as a treatment planning system (TPS), must be used to facilitate the review and editing of contours generated by DV.Target.

DV.Target can delineate the following 49 OARs distributed across three anatomic sites (**Table 2**):

Table 2. *List of OARs delineated by DV.Target across three anatomic sites.*

Anatomic Site	OARs	No. of OARs
Head & Neck	Brachial plexus, Brain Stem, Constrictor naris, Ear Left, Ear Right, Eye Left, Eye Right, Hypophysis, Larynx, Lens Left, Lens Right, Mandible, Optic chiasm, Optic nerve Left, Optic nerve Right, Oral cavity, Parotid Left, Parotid Right, Sublingual gland, Submandibular gland Left, Submandibular gland Right, Spinal Cord, Temporal Lobe Left, Temporal Lobe Right, Temporomandibular joint Left, Temporomandibular joint Right, Thyroid, Trachea	28
Thorax	Esophagus, Heart, Lung Left, Lung Right, Spinal Cord, Trachea	6
Abdomen & Pelvis	Bladder, Duodenum, Gallbladder, Femur Left, Femur Right, Kidney Left, Kidney Right, Large Bowel, Liver, Pancreas, Rectum, Small Bowel, Spleen, Spinal Cord, Stomach	15

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6. Comparison of Indications for Use with Predicate Device

Both the proposed and predicate devices are software applications designed to be used by trained medical professionals within a hospital environment, and are indicated for the creation of contours for use in clinical workflows for the purpose of radiation therapy treatment planning.

Both the predicate and proposed devices support contouring based on machine learning techniques, whereas the predicate device additionally supports atlas-based contouring and registration-based re-contouring.

Both the proposed and predicate devices are designed to interoperate via DICOM objects and to network with other DICOM capable devices such as PACS and Radiation Treatment Planning Systems.

Both the proposed and predicate devices do not facilitate the display or visualization of the data by users. Reviewing and editing of contouring results cannot be performed within both devices.

Both the proposed and predicate devices require users to confirm and review generated contours in a separate image visualization system.

In summary, DeepVoxel Inc. believes the intended use of the proposed device is substantially equivalent to the predicate device, excepting the registration-based features in the predicate device, which are not applicable to the proposed device.

Table 3. *Comparison of Indications for Use with Predicate Device.*

	Proposed Device	Predicate Device
Indications for use	• DV.Target is a software application that enables the routing of image data (CT Images) to automatic image processing workflows, using machine learning learning-based algorithms to automatically delineate OARs (Organs-at-risk). Contours generated by DV.Target may be used as an input to clinical workflows for treatment planning in radiation therapy. • DV.Target is intended to be used by trained medical professionals including radiologists, radiation oncologists, dosimetrists, and physicists.	• Workflow Box is a software system designed to allow users to route DICOM-compliant data to and from automated processing components. Supported modalities include CT, MR, RTSTRUCT. • Workflow Box includes processing components for automatically contouring imaging data using deformable image registration to support atlas-based contouring, re-contouring of the same patient and machine learning based contouring. • Workflow Box is a data routing and image processing tool which automatically applies contours to data which is sent to one or more of the included image processing workflows.

	• DV.Target does not provide a user interface for data visualization. The image data uploaded, auto-contouring results and other functionalities are managed via an administration interface. Thus, it is required that DV.Target be used in conjunction with appropriate software, such as a treatment planning system (TPS), to review, edit and approve for all contours generated by DV.Target. • DV.Target is only intended for normal organ contouring, not for tumor or clinical target volume contouring.	Contours generated by Workflow Box may be used as an input to clinical workflows including, but not limited to, radiation therapy treatment planning. • Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components, for example image visualization software must be used to facilitate the review and edit of contours generated by Workflow Box component applications. • Workflow Box is intended to be used by trained medical professionals. • Workflow Box is not intended to automatically detect lesions.

7. Comparison of Technological Characteristics with Predicate Device

Table 4. *Comparison of Technological Characteristics with Predicate Device.*

Characteristic	Proposed Device	Predicate Device
Device Name	DV.Target	Workflow Box (K181572)
Regulation No.	No. 21CFR 892.2050	No. 21CFR 892.2050
Classification Name	Picture archiving and communications system	Picture archiving and communications system
Product Code	QKB	LLZ
Class	II	II
Target Population	Any patient type for whom relevant modality scan data is available.	Any patient type for whom relevant modality scan data is available.
Where Used	Clinical/Hospital environment	Clinical/Hospital environment
Target Users	Designed to be used by trained clinicians	Designed to be used by trained clinicians
Energy Used and/or Delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	None – software only application. The software application does not deliver or depend on energy delivered to or from patients

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Data Visualization	None – the proposed device has no data visualization functionality. All data processing is automated and does not require user interaction. A control interface is provided for system administration and configuration only.	None – the predicate device has no data visualization functionality. All data processing is automated and does not require user interaction. A control interface is provided for system administration and configuration only.
Regions and Volumes of Interest (ROI)	Machine learning-based contouring	Atlas-based contouring, registration-based re-contouring, machine learning-based contouring
ROI measurements and quantification	Not applicable	Not applicable
Image Registration	Not applicable	Registration for the purposes of re-planning/re-contouring and atlas based contouring.
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801
Operating System	Ubuntu, Windows	Windows
Algorithm	Machine learning-based	Machine learning-based and Atlas-based
Supported Modalities	CT, RTSTRUCT	CT, MR, RTSTRUCT
Reporting and data routing	Supports automatic routing images to processing workflow. No customized options for the user	Supports routing and distribution of images to other DICOM nodes including to custom executables determined by the user
Communications/ Networking	TCP/IP and SCP	TCP/IP and SCP
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required	No Limitation on scanner model, DICOM 3.0 compliance required
Compatible Treatment Planning System	No Limitation on TPS model, DICOM 3.0 compliance required	No Limitation on TPS model, DICOM 3.0 compliance required

The predicate device and the proposed device are both standalone software applications for medical image processing. Both devices process DICOM image data and include design features to enable automatic delineation of contours on input image data.

Both the proposed and predicate devices utilize algorithms to automatically generate regions of interest structures/contours. The predicate device also utilizes image registration for atlas-based contouring and re-contouring.

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Both devices are compatible with the same use environments and utilize the same networking technology. The predicate device operates on Microsoft Windows operating systems, while the proposed device can operate on both Microsoft Windows and Ubuntu (a Linux distribution) operating systems.

19 OARs (hereinafter referred to as "overlapping OARs") are delineated by both the proposed and predicate devices. However, there are additional 30 OARs only delineated by the proposed device, and 16 OARs only delineated by the predicate device.

The proposed device offers a subset of the image processing technical features presented by the predicate device. The shared features are substantially equivalent to the predicate device and do not present any additional or new risks when compared to the predicate device.

8. Non-Clinical Test Conclusion

In summary, we have conducted three Comparison Studies to evaluate the performance of the proposed device:

- Comparison Study 1: Conducted between the proposed and predicate devices on a public validation dataset (64% are from the US) to evaluate the auto-contouring accuracy of 19 overlapping OARs (OARs delineated by both devices).
- Comparison Study 2: Conducted between the proposed and predicate devices on an in-house clinical dataset to evaluate the auto-contouring accuracy of the overlapping OARs.
- Comparison Study 3: Conducted between the proposed device and a reference device (MIM – MRT Dosimetry 510(k) Number K182624) on the public validation data (64% are from the US) to evaluate the auto-contouring accuracy of 30 non-overlapping OARs (OARs delineated by the proposed device, but not by the predicate).

The validation data used in these studies consists of two independent datasets: a) a public dataset collected from a large medical images archive --- TCIA and b) a clinical in-house dataset collected retrospectively from the City of Hope (our primary validation site). A comprehensive characteristic analysis of validation data to demonstrate the representativeness of the intended patient population is presented and related backgrounds are introduced. The ground truth OARs contours on the public validation data were generated from the consensus of three board-certified physicians. The ground truth contours on the in-house clinical data (collected retrospectively) were based on actual clinical contouring results.

All validation data described above were invisible in model training. The Dice-Sørensen coefficients (DICE score) were calculated and used to evaluate contouring accuracies by comparing device-generated contours with ground truth contours. A systematic statistical methodology, including data presentation (histogram, Box and Whisker plot, and Bland-Altman plot) and statistical inferences

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(i.e. the non-inferiority tests), is established as the guidelines for data analysis in the three Comparison Studies.

We have presented detailed results from the three Comparison Studies. In each of the studies, we observed the following results: a) The DICE scores from the proposed and the predicate/reference devices both have a central tendency (DICE Score differences can be approximated by the normal distribution) and have a good agreement with each other (from histograms and Bland-Altman plots). b) The DICE scores of the proposed device are generally higher than those of the predicate/reference device (from the Box and Whisker plots). c) The confidence interval of performance differences between the proposed and the predicate/reference devices are within the non-inferiority margin for all compared OARs. Hence the statement that the proposed device is non-inferior to the predicate/reference device is established. Additionally, we demonstrate that the performance of the proposed device on the non-overlapping OARs is similar to its performance on the overlapping OARs (Comparison Study 3b).

We draw the following conclusions from these studies:

- DV.Target is non-inferior to the predicate device Mirada on all 19 overlapping OARs. This conclusion is supported by Comparison Studies 1&2, based on validation data from different sites and with independent annotations.
- DV.Target is non-inferior to the reference device MIM on the 30 non-overlapping OARs. The performance of DV.Target on the non-overlapping OARs is similar to its performance on the overlapping OARs. This is supported by Comparison Studies 3a & 3b.

According to these results, we conclude that the performance of the proposed device is substantially equivalent to the performance of the predicate device.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, DeepVoxel Inc. believes that the proposed device can be determined to be Substantially Equivalent (SE) to the predicate device.