Perception Vision Medical Technologies LTD.CO.
Chuanji Huang
Regulatory Affairs Manager   December 3, 2021
Room 306, First Phase Office Building
No. 12, Yuyan Road, Huangpu District
Guangzhou, Guangdong 510530
China

Re: K210916
    Trade/Device Name: PVmed Contouring Software
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Medical image management and processing system
    Regulatory Class: Class II
    Product Code: LLZ
    Dated: October 29, 2021
    Received: November 3, 2021

Dear Chuanji Huang:

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: 06/30/2023

See PRA Statement below.

510(k) Number *(if known)*
K210916

Device Name

PVmed Contouring Software

Indications for Use *(Describe)*
PVmed Contouring Software is a software package. It allows the display, annotation, volume operation, volume rendering, and fusion of medical CT images as an aid during use by radiation therapy planning. it is limited to auto-contouring of OARs for head and neck, chest and abdomen, abdomen and pelvis.

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.

K210916

Premarket Notification Traditional 510(k) Submission
PVmed Contouring Software
Section 5: 510(k) Summary
Ref No.: TF-FDA- Contouring -005

Section 5: 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

The assigned 510(k) Number: K210916

5.1 Submitter

510(k) owner's name: Perception Vision Medical Technologies LTD.CO.

Address: Room 306, First Phase Office Building, No. 12, Yuyan Road, Huangpu District Guangzhou, Guangdong, 510530, P. R. China

Tel: +86-20-34329782

Fax: +86-20-34329782

Contact Person: Chuanji Huang

Email: RA@pvmedtech.com

Date Prepared: October 28, 2021

5.2 Device

Name of Device: PVmed Contouring Software

Common Name: PVmed Contouring Software

Model: PVmed Contouring B

Classification Name: Medical image management and processing system

Regulation No: 21 CFR892.2050

Regulatory Class: Class ‖

Product Code: LLZ

5.3 Predicate Device

PVmed Contouring Software is substantially equivalent to the following legally marketed predicate devices. This predicate device has not been subject to any design related recalls.

Item	Predicate Device
510(k) Submitter/Holder	Varian Medical Systems, Inc.
510(k) Number	K173636
Device Name	Velocity
Regulation Name	Medical image management and processing system
Product Code	LLZ
Regulation Class	Class II
Regulation Number	21 CFR892.2050

5.4 Device Description

The device, PVmed Contouring Software is a software package. It allows the display, annotation, volume operation, volume rendering, and fusion of medical CT images as an aid during use by radiation therapy planning. it is limited to auto-contouring of OARs for head and neck, chest and abdomen, abdomen and pelvis.

The product mainly has the following image processing functions:
Support contour drawing of organs at risk in head and neck, chest and abdomen, abdomen and pelvis.

It also has the following general functions:
- Receive, add/edit/delete, transmit, input/export, medical images and DICOM data;
- Data set management, patient data management;
- Review of processed images;
- Image fusion;
- Open and Save of files.

5.5 Indications for Use Statement

PVmed Contouring Software is a software package. It allows the display, annotation, volume operation, volume rendering, and fusion of medical CT images as an aid during use by radiation therapy planning. it is limited to auto-contouring of OARs for head and neck, chest and abdomen, abdomen and pelvis.

5.6 Substantial Equivalence Discussion

Table 5.1 Summary Comparison Table

Comparison Elements	Subject Device	Predicate Device	Discussion of difference
Basic Information			
Device Name	PVmed Contouring Software	Velocity	/
510(k) No	/	K173636	/
Regulation No	21 CFR 892.2050	21 CFR 892.2050	Same
Regulation Description	Medical image management and processing system	Picture archiving and communications system	Same
Classification name	System, Image Processing,	System, Image Processing,	Same

Comparison Elements	Subject Device	Predicate Device	Discussion of difference
	Radiological	Radiological	
Classification	Class II	Class II	Same
Product code	LLZ	LLZ	Same
Indications for use	PVmed Contouring Software is a software package. It allows the display, annotation, volume operation, volume rendering, and fusion of medical CT images as an aid during use by radiation therapy planning. it is limited to auto-contouring of OARs for head and neck, chest and abdomen, abdomen and pelvis.	Velocity is a software package that provide the physicians a means for comparison of medical data including imaging data that is DICOM. It allows the display, annotation, volume operation, volume rendering, registration, and fusion of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Velocity is not intended for mammography.	Both use for anatomy boundary contours.
General Usage/ Performance Features			
Image Study Importation	Yes CT, Query/Retrieve	Yes DICOM, PET/SPECT/CT/MRI Dose, Query/Retrieve automation added in 4.0	The predicate device support Dose, The subject Device doesn't support DICOM,PET/SPECT/MRI.
Image Structure Import, Save & Export	Yes	Yes	Same
Volume rendering	Yes Image 3D rendering	Yes 4D Cine Volume support in 4.0.0	Both support volume rendering.
Advanced Visualization	Yes	Yes	Same

Comparison Elements	Subject Device	Predicate Device	Discussion of difference
and Navigation Features			
Volume Operations	No	Yes	The subject Device doesn't support.
Diagnostic Image registration	Yes	Yes	Same
Image Fusion	Yes	Yes	Same
Contouring	Yes	Yes	The subject device only allows for auto contouring OARs.
Manual Contouring Tools	Yes	Yes	Same
Image Analysis	No	Yes	The subject Device doesn't support.
Plan Review of imported plans or created dose composites	No	Yes	The subject Device doesn't support.
Oncology workflow automation	No	Yes	The subject Device doesn't support.
Image/ROI Export to DICOM RT	Yes	Yes	Same
Secure login and data storage	Yes	Yes	Same
Operating System Platform	Supports Linux, Windows 10 and above and Mac OS 10.14	Microsoft Windows 7 & 10 (64 bit only)/ Windows Server 2008R2 (Citrix), 2012R2, 2016 MAC OS 10.12 Sierra, macOS 10.13 High Sierra	Both support Windows and Mac OS. The Windows and Mac OS are updating. The risk of the Subject Device was verified(Section 21-3 System Test)
Multimodality DICOM Import			
Import and display DICOM CT, MR, DS, PET, RTS, RTP	Supports DICOM CT	Yes	The subject Device doesn't support MR,PET DS and RTP
Advanced Visualization & Navigation			
General image viewer with view layout selection and toolbars	Yes	Yes	Same
Volume Operations			
User scaling of image volumes	No	Yes	The subject Device doesn't support.
Biological Effective Dose (BED) Scaling	No	Yes	The subject Device doesn't support.
Y-90 Microsphere Dosimetry –conversion of SPECT to DS	No	Yes	The subject Device doesn't support.

Automated Image-based Registration			
Comparison Elements	**Subject Device**	**Predicate Device**	**Discussion of difference**
Manual registration editing	Yes	Yes	Same
Auto Rigid Registration	Yes	Yes	Same
Deformable Registration	Yes	Yes	Same
Inverse deformable registration	Yes	Yes	Same
Inverse deformable registration	No	Yes	The subject Device doesn't support.
Structure Guided deformable	No	Yes	The subject Device doesn't support.
Segmentation			
Manual Contouring tools	Yes	Yes	Same
Image analysis with volumetric graphs			
Histograms and Voxel Assessment graphs	No	Yes	The subject Device doesn't support.
DVH statistics display	No	Yes	The subject Device doesn't support.
Plan Review			
Storage and display of DICOM RT Plans	No	Yes	The subject Device doesn't support.
Lesion volume tracking by associating structure with name tag	No	Yes	The subject Device doesn't support.
Navigator Semi-Automated Workflows			
Semi-automatic workflows to assist with common clinical image registration & analysis tasks	No	Yes	The subject Device doesn't support.
Adaptive Navigators to assist in offline dose review: includes workflows to create adaptive CT based on CBCT registration, copy plan to adaptive CT, and compare dose.	No	Yes	The subject Device doesn't support.
Security			
Logging of database activity	Yes	Yes	Same

The features table lists the features of PVmed Contouring Software, as compared to the predicate device.

Compared with the predicate devices, Velocity (K173636), the Indications for Use, Performance Features are substantial equivalence.

PVmed Contouring Software is substantially equivalent to the cited predicate device. Differences in the design and performance from the predicate devices do not affect either the safety or the effectiveness of PVmed Contouring Software for its intended use.

5.7 Performance Date

The following performance data were provided in support the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The software for this device was considered as a 'major' level of concern.

Summary of Non-Clinical Trial

In order to verify the drawing accuracy of the software, the drawing results of organs at risk using the software were compared and evaluated with the drawing results manually drawn by radiotherapy doctors. The test selected CT images of who were admitted to 5 hospitals for radiotherapy in the past 3 years. The test group was delineated by software, and the radiotherapy doctors with more than 5 years of practice were delineated as the control group. The effectiveness evaluation indexes of the trial were delineated dice similarity coefficient. The results show that the software can meet the requirements of drawing accuracy.

Summary of Clinical Trial

No clinical tests have been included in this pre-market submission.

5.8 Conclusions

PVmed Contouring Software has the same indications for use, intended use and technological characteristics as the predicate device. All technological characteristics of the PVmed Contouring Software are substantially equivalent to the predicate device.

Where operational and performance differences exist between the proposed device and the predicate device, performance testing demonstrated that these differences do not adversely affect the device's safety and effectiveness.

Results from Verification and Validation testing demonstrate that the product met defined user needs and defined design input requirements.

PVmed therefore considers PVmed Contouring Software software to be substantially equivalent and to perform at least as well as the predicate device.