



Pymedix  
% Trey Thorsen  
RA Consultant  
Lean RAQA  
131 E Loch Lomond Pl  
ORO VALLEY, AZ 85737

March 6, 2024

Re: K233572  
Trade/Device Name: Autofuse  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical Image Management And Processing System  
Regulatory Class: Class II  
Product Code: LLZ  
Dated: January 30, 2024  
Received: February 2, 2024

Dear Trey Thorsen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "Lora D. Weidner". The signature is fluid and cursive, with a large initial "L".

Lora D. Weidner, Ph.D.  
Assistant Director  
Radiation Therapy Team  
DHT8C: Division of Radiological Imaging  
and Radiation Therapy Devices  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K233572

Device Name

Autofuse

Indications for Use (Describe)

Autofuse is a software package that provides physicians a means for comparison of medical data including imaging data that is DICOM compliant. 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. Autofuse is not intended for mammography.

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

## 1. APPLICANT INFORMATION

| Pymedix Company Contact |                                                                    |
|-------------------------|--------------------------------------------------------------------|
| Name:                   | Kris Huang                                                         |
| Title:                  | Co-CEO, CTO                                                        |
| Phone Number:           | 513-693-5845                                                       |
| Email:                  | <a href="mailto:kris.huang@pymedix.com">kris.huang@pymedix.com</a> |
| Official Correspondent  |                                                                    |
| Name:                   | Trey Thorsen                                                       |
| Title:                  | RA consultant                                                      |
| Phone Number:           | 850-450-3932                                                       |
| Email:                  | <a href="mailto:treyt@leanraqa.com">treyt@leanraqa.com</a>         |

## 2. DEVICE INFORMATION

|                      |                                                |
|----------------------|------------------------------------------------|
| Device Name:         | Picture Archiving and Communication System     |
| Common Name:         | Medical Imaging Software                       |
| Classification Name: | Medical image management and processing system |
| Model(s):            | Autofuse                                       |
| Regulation Number:   | 21 CFR § 892.2050                              |
| Product Code:        | LLZ                                            |
| Class:               | II                                             |

## 3. PREDICATE DEVICES

| Predicate Type   | 510(k) Number | Name of Device                           | Name of Manufacturer            |
|------------------|---------------|------------------------------------------|---------------------------------|
| Primary Device   | K081076       | Velocity AIS                             | Velocity Medical Solutions, LLC |
| Reference Device | K201607       | Eclipse Treatment Planning System, v16.1 | Varian Medical Systems, Inc     |

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## 4. DEVICE DESCRIPTION

Autofuse is a software application providing relevant tools for Radiotherapy professionals to use while creating treatment plans.

The Autofuse device is a Picture Archiving and Communication System (medical imaging software). Autofuse provides medical image processing designed to facilitate the oncology or other clinical specialty workflow by allowing the comparison of medical imaging data from different modalities, points in time, and / or scanning protocols. The product provides users with the means to display, co-register and analyze medical images from multiple modalities including PET, CT, RT Dose and MR; draw Regions of Interest (ROI); and import / export results to/from commercially available radiation treatment planning systems and PACS devices. Co-registration includes deformable registration technology that can be applied to DICOM data including diagnostic and planning image volumes, structures, and dose.

Autofuse is used as a stand-alone application on recommended Off-The-Shelf (OTS) computers supplied by the company or by the end-user.

## 5. INDICATIONS FOR USE

Autofuse is a software package that provides physicians a means for comparison of medical data including imaging data that is DICOM compliant. 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.

Autofuse is not intended for mammography.

## 6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

| Characteristic      | Proposed Device                                                                                   | Predicate Device                                                                                  | Remark  |
|---------------------|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|---------|
| Device              | Autofuse                                                                                          | Velocity AIS                                                                                      | N/A     |
| Manufacturer        | Pymedix, Inc.                                                                                     | Velocity Medical Solutions, LLC                                                                   | N/A     |
| 510(k) Number       | TBD                                                                                               | K081076                                                                                           | N/A     |
| Product Common Name | Picture Archiving and Communication System (Medical Imaging Software)                             | Picture Archiving and Communication System (Medical Imaging Software)                             | Same    |
| Product Code        | LLZ                                                                                               | LLZ                                                                                               | Same    |
| Classification      | II                                                                                                | II                                                                                                | Same    |
| Device description  | Autofuse is a software application providing relevant tools for Radiotherapy professionals to use | Velocity is a software application providing relevant tools for Radiotherapy professionals to use | Similar |

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|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>while creating treatment plans.</p> <p>The Autofuse device is a Picture Archiving and Communication System (medical imaging software). Autofuse provides medical image processing designed to facilitate the oncology or other clinical specialty workflow by allowing the comparison of medical imaging data from different modalities, points in time, and / or scanning protocols. The product provides users with the means to display, co-register and analyze medical images from multiple modalities including PET, CT, RT Dose and MR; draw Regions of Interest (ROI); and import / export results to/from commercially available radiation treatment planning systems and PACS devices. Co-registration includes deformable registration technology that can be applied to DICOM data including diagnostic and planning image volumes, structures, and dose.</p> <p>Autofuse is used as a stand-alone application on recommended Off-The-Shelf (OTS) computers supplied by the company or by the end-user.</p> | <p>while creating treatment plans.</p> <p>The Velocity device is a Picture Archiving and Communication System (medical imaging software). Velocity provides medical image processing designed to facilitate the oncology or other clinical specialty workflow by allowing the comparison of medical imaging data from different modalities, points in time, and / or scanning protocols. The product provides users with the means to display, co-register and analyze medical images from multiple modalities including PET, SPECT, CT, RT Dose and MR; draw Regions of Interest (ROI), calculate and report relative differences in pixel intensities, Standardized Uptake Value (SUV) or other values within those regions; and import / export results to/from commercially available radiation treatment planning systems and PACS devices. Co-registration includes deformable registration technology that can be applied to DICOM data including diagnostic and planning image volumes, structures, dose, and automatic anatomical</p> |  |
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|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
|                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>atlas-based segmentation tools.</p> <p>Velocity is used as a stand-alone application on recommended Off-The-Shelf (OTS) computers supplied by the company or by the end-user.</p>                                                                                                                                                                                                                                                                                                             |                                                                                                                                  |
| Indications for Use                       | <p>Autofuse is a software product that provides physicians a means for comparison of medical data including imaging data that is DICOM compliant. 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.</p> <p>Autofuse is not intended for mammography.</p> | <p>VelocityAIS (VelocityAI) is a standalone software product that provides the physician a means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, annotating, volume rendering, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties.</p> <p>VelocityAIS (VelocityAI) is not intended for mammography diagnosis.</p> | Similar                                                                                                                          |
| <b>General Usage/Performance Features</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                  |
| Image Study Importation                   | CT/MR/PET                                                                                                                                                                                                                                                                                                                                                                                                                                  | DICOM, PET/SPECT/CT/MRI; Dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Similar. The most commonly used imaging modalities used in radiation treatment planning are DICOM-format CT, MR, and PET images. |

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|---------------------------------------------------------------------|---------------------------------------|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                     |                                       |                                       | Autofuse does allow import of DICOM-RT Dose, but it is considered a DICOM-RT object associated with a scan, not an imaging modality itself. This difference does not bring up any new questions of safety or efficacy. |
| Image Structure Import, Save & Export to Treatment Planning Systems | Yes                                   | Yes                                   | Same                                                                                                                                                                                                                   |
| Volume Rendering                                                    | Yes                                   | Yes                                   | Same                                                                                                                                                                                                                   |
| Advanced Visualization and Navigation Features                      | Yes                                   | Yes                                   | Same                                                                                                                                                                                                                   |
| Volume Operations                                                   | No                                    | No                                    | Same                                                                                                                                                                                                                   |
| Diagnostic Image Registration                                       | Yes                                   | Yes                                   | Same                                                                                                                                                                                                                   |
| Image Fusion                                                        | Yes; Anatomical and Functional Images | Yes; Anatomical and Functional Images | Same                                                                                                                                                                                                                   |
| ROI & Contouring                                                    | Yes                                   | Yes                                   | Same                                                                                                                                                                                                                   |
| Manual Contouring Tools                                             | Yes                                   | Yes                                   | Same                                                                                                                                                                                                                   |
| Image Analysis                                                      | Yes                                   | Yes                                   | Same                                                                                                                                                                                                                   |
| Plan Review of Imported Plans or Created Dose Composites            | No                                    | No                                    | Same                                                                                                                                                                                                                   |
| Oncology Workflow Automation                                        | No                                    | No                                    | Same                                                                                                                                                                                                                   |
| Image/ROI Export to DICOM RT                                        | Yes                                   | Yes                                   | Same                                                                                                                                                                                                                   |
| Secure Login and Data Storage                                       | No                                    | Yes                                   | Velocity uses an application-level login. Autofuse is intended to run on a secure                                                                                                                                      |

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|--------------------------------------------------------------|--------------|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                              |              |                                                                  | workstation and logs OS-level information of the user logged in and running the application. Data storage and user authentication is handled by the underlying workstation OS, not the Autofuse application. This difference does not bring up any new questions of safety or efficacy. |
| Operating System Platform                                    | Ubuntu 22.04 | Microsoft Windows XP 32 bit only/ Windows 7, Vista, MAC OSX 10.6 | Autofuse is intended for use in a secure Linux-based computing environment. This difference does not bring up any new questions of safety or efficacy.                                                                                                                                  |
| <b>Multimodality DICOM Import</b>                            |              |                                                                  |                                                                                                                                                                                                                                                                                         |
| Import and Display DICOM CT, MR, DS, PET, RTS, RTP           | Yes          | Yes                                                              | Same                                                                                                                                                                                                                                                                                    |
| <b>Advanced Visualization and Navigation</b>                 |              |                                                                  |                                                                                                                                                                                                                                                                                         |
| General Image Viewer with View Layout Selection and Toolbars | Yes          | Yes                                                              | Same                                                                                                                                                                                                                                                                                    |
| User Scaling of Image Volumes                                | No           | No                                                               | Same                                                                                                                                                                                                                                                                                    |
| Biological Effective Dose (BED) Scaling                      | No           | No                                                               | Same                                                                                                                                                                                                                                                                                    |
| Y-90 Microsphere Dosimetry                                   | No           | No                                                               | Same                                                                                                                                                                                                                                                                                    |

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|----------------------------------------------------------------------|-----|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| conversion of SPECT to DS                                            |     |     |                                                                                                                                                                                                                                   |
| <b>Automated Image-Based Registration</b>                            |     |     |                                                                                                                                                                                                                                   |
| Manual Registration Editing                                          | No  | Yes | Autofuse does not allow manual registration. AAPM TG-132 states “direct, unguided manual adjustment of a deformation vector field is not recommended”. This difference does not bring up any new questions of safety or efficacy. |
| Auto Rigid Registration                                              | Yes | Yes | Same                                                                                                                                                                                                                              |
| Deformable Registration                                              | Yes | Yes | Same                                                                                                                                                                                                                              |
| Inverse Deformable Registration                                      | No  | No  | Same                                                                                                                                                                                                                              |
| Structure Guided Deformable                                          | No  | No  | Same                                                                                                                                                                                                                              |
| <b>Segmentation (Manual Contouring Tools and Atlas Segmentation)</b> |     |     |                                                                                                                                                                                                                                   |
| Manual Contouring Tools                                              | Yes | Yes | Same                                                                                                                                                                                                                              |
| Atlas Auto-Segmentation                                              | No  | Yes | Autofuse does not contain or use atlases for auto-segmentation. This difference does not bring up any new questions of safety or efficacy.                                                                                        |
| <b>Image Analysis with Volumetric Graphs</b>                         |     |     |                                                                                                                                                                                                                                   |
| Histograms and Voxel Assessment Graphs                               | Yes | Yes | Same                                                                                                                                                                                                                              |

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DVH Statistics Display                                                                                                                                                | Yes                                                                     | Yes | Same                                                                                                                                                         |
| <b>Plan Review</b>                                                                                                                                                    |                                                                         |     |                                                                                                                                                              |
| Storage and Display of DICOM RT Plans                                                                                                                                 | No                                                                      | No  | Same                                                                                                                                                         |
| Lesion Volume Tracking by Associating Structure with Name Tag                                                                                                         | No                                                                      | No  | Same                                                                                                                                                         |
| <b>Navigator Semi-Automated Workflows</b>                                                                                                                             |                                                                         |     |                                                                                                                                                              |
| Semi-automatic Workflows to Assist with Common Clinical Image Registration & Analysis Tasks                                                                           | No. Image registration is fully automated with no user-facing workflow. | No  | Same                                                                                                                                                         |
| 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                                                                      | No  | Same                                                                                                                                                         |
| <b>Security</b>                                                                                                                                                       |                                                                         |     |                                                                                                                                                              |
| Logging of Database Activity                                                                                                                                          | No                                                                      | Yes | Database activity is timestamped, tagged by user and logged for all transactions. This difference does not bring up any new questions of safety or efficacy. |

## 7. PERFORMANCE DATA

### 7.1 Non-clinical performance Data

Software Verification and Validation Testing Software verification and validation was 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 primary objective of the design validation testing process was to ensure

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documented confirmation that the device specifications meet user needs and the intended use through thorough testing in a simulated environment as part of the Design Control Process. Test results demonstrate conformance to applicable requirements and specifications.

The following references provide external standards and guidelines that are used, in part, for the definition of the guidelines provided in this document:

- 21 CFR Part 820, Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, US Food and Drug Administration
- ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes, International Organization for Standardization
- ISO/DIS 10013 Quality management systems — Guidance for documented information, International Organization for Standardization
- Glossary of Computerized System and Software Development Terminology, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs, Food and Drug Administration, August 1995.
- AAPM Report No. 062 - American Association of Physicists in Medicine Radiation Therapy Committee Task Group 53: Quality assurance for clinical radiotherapy treatment planning (1998) ICRU Report 83 - Prescribing, Recording, and Reporting Intensity-Modulated Photon-Beam Therapy (IMRT)
- AAPM Report No. 132 - Use of image registration and fusion algorithms and techniques in radiotherapy: Report of the AAPM Radiation Therapy Committee Task Group No. 132 (2017)

Non-clinical validation testing was performed in the Staging Environment (SE), which consists of a network of virtual machines (VMs) within a Kernel Virtual Machine (KVM) hypervisor. The network of VMs is designed to mimic a typical clinical set up including a departmental CT scanner and a radiology PACS communicating with unencrypted DIMSE communications or TLS-encrypted DIMSE communications.

## 7.2 Biocompatibility

Not applicable. Autofuse is software.

## 7.3 Clinical performance data

No clinical study is included in this submission.

## 8. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is substantially equivalent, and performs as well as or better than the predicate device.