VUZE Medical Ltd.
% Clay Anselmo
Principal Quality and Regulatory Consultant
Shriner & Associates, Inc.
429 Whitepine Creek Road
Trout Creek, Montana 59874

May 9, 2024

Re: K232976
Trade/Device Name: VUZE System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 2, 2024
Received: April 2, 2024

Dear Clay Anselmo:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232976

Device Name
VUZE System

Indications for Use *(Describe)*
The VUZE System is intended to enable users to load pre-operative 3D images and planning data and register and overlay this data in real time with intra-operative 2D radiographic images of the same anatomy to support device guidance during interventional spinal procedures. The system also offers pre-operative surgical planning including implant sizing, entry location, and trajectory determination along with intra-operative guidance and tool trajectory / position confirmation.

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 – K232976

Introduction:

This document contains the 510(k) Summary for the VUZE Medical - VUZE System. The content of this summary is based on the requirements set forth in 21 CFR 807.92(c).

Submitter Information:

Applicant / Manufacturer Name and Address	VUZE Medical Ltd. 3/84 Rav Ashi St. Tel Aviv 6939537, Israel
510(k) Submitter / Preparer	Clay Anselmo Principal Quality and Regulatory Consultant Shriner & Associates 429 Whitepine Creek Road Trout Creek, MT 59874 clay.anselmo@shrinerandassociates.com
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Date prepared	08-May-2024

Device Identification

Trade names	VUZE System
Common name	VUZE Medical Imaging System for spinal interventions
Classification name	Medical Image Management and Processing System
Regulation Number	21 CFR Part 892.2050
Classification	Class II
Product Code	Primary: LLZ

Predicate Device

Trade names:	VUZE System
510(k) number:	K210830

Device Description:

The VUZE System (the “System”) enables users to load 3D images and planning data then register and overlay this data in real time with intra-operative 2D radiographic images of the same anatomy. The System supports device guidance during minimally invasive spinal surgery, including the stabilization of the spine by means of fixation, fixation coupled with fusion, vertebroplasty or kyphoplasty. Applicable vertebrae are within the range of S1 through T7.

The System offers optional pre-operative surgical planning including implant sizing, entry location and trajectory determination, along with intra-operative guidance and tool trajectory/position confirmation by displaying a graphical representation of a tool tracked by intra-operative 2D images onto a patient’s pre-operative 3D images.

The System’s main components include:

- A workstation running the VUZE Planning and Procedure software (pre-installed)
- A housing for the workstation, with a front door for user access as well as a back service door
- A 32” touchscreen
- A mouse
- An isolation transformer
- An internal video acquisition device (frame grabber)
- A minimal-footprint, wheeled cart on which the above-listed items are placed.
- DVI cable with galvanic isolator
- An optional standalone planning station (planning software running on a commercial PC with identified specifications)
- Optional C-arm orientation sensors (3), charger, and associated Bluetooth dongle (Note: The orientation sensor may also be referred to under an acronym of IMU)
- Optional OTS foot pedal and associated Bluetooth dongle

Indications for Use:

The VUZE System is intended to enable users to load pre-operative 3D images and planning data and register and overlay this data in real time with intra-operative 2D radiographic images of the same anatomy to support device guidance during interventional spinal procedures. The system also offers pre-operative surgical planning including implant sizing, entry location, and trajectory determination along with intra-operative guidance and tool trajectory / position confirmation.

Technological Characteristics Comparison:

Substantial Equivalence: The VUZE System is substantially equivalent to the original VUZE System (a.k.a. original device) K210830.

The 510(k) Substantial Equivalence Decision-making Process (detailed) from FDA Guidance - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] was followed as described below:

- The modified VUZE System has the same intended use and the same indications for use as the Predicate device (original version of the VUZE System).
- The VUZE System uses identical fundamental technology as the Predicate device and very similar detailed technological solutions.
- The following summary of technological changes from the originally cleared device and the modified VUZE System are being made through this 510(k):

    - **Planning Software:**
        - Added option for planning-only station that contains only the planning software which runs on commercial PC meeting certain specified requirements. Option includes export to USB functionality for transferring planning data to VUZE System.
        - Elimination of the need to generate pre-operative data during planning. New feature allows DRR generation in real-time during procedure.
        - Addition of a new feature incorporating horizontal line angle control into the Coronal cross-section, supplementing the existing Sagittal cross-section controls.
        - Add a check of 3D scan slice thickness to ensure it is equal to or greater than slice interval. Discard scans that do not meet this requirement.
        - Add feature that requires the user to indicated whether the skin level is visible in the axial view or not.
        - Add support for loading DICOM-CTs generated by 3D C-arm machines (CBCT).
        - Minor graphical user interface improvements for usability (e.g. view zoom, display simplifications, display pixel spacing, reset button addition, button re-arrangement).
        - Resolution of non-safety related software anomalies.

    - **VUZE System and Procedure Software**
        - Implement a modification to the CT to X-ray registration algorithm to replace the reliance on pre-operative data for generating the initial-guess registration. This algorithm performs in real-time similar calculations that were previously done preoperatively.
        - Implement a registration success score to assess the System’s confidence in the CT to X-ray registration result. This score assesses the System's confidence in the registration and establishes a specific threshold to determine registration failure.
        - Addition of a Bluetooth C-arm orientation sensor and associated Bluetooth dongle to allow compatibility with additional X-ray systems.

- Deprecation of the previous ML algorithm for determining window size parameters. Same functionality is now done by a traditional algorithm that calculates the filter for several window sizes and chooses the best one.
- Add option to load CT images and planning data from USB media.
- Add support for additional C-arm systems for 2D X-ray image acquisition:
  - Philips Zenition 70
  - GE: OEC Elite CFD
  - Ziehm: Vision FD and Vision RFD 3D (2 different Flat Detector types)
- Add support for Siemens NXS protocol for image acquisition via a LAN connection as an alternative to using a frame grabber. This option is available only the Siemens Cios Spin C-arms.
- Add a new “live DRR” display, also known as "Simulated X-ray view" that activates when the C-arm rotates and displays a 2D projection image derived from the 3D CT / CBCT scan data in accordance with the current angles of the C-arm.
- Add a verification and associated alert to ensure that tool length marking is not shorter than 40mm and that the position of the marked tool is not further than 200 pixels from that marked in the planning data.
- Add a feature to enable users to instantly view the newly acquired X-ray image prior to its processing, with no dark background.
- Add a feature that allows the user to verify proper positioning of all the tools (e.g. k-wires prior to screw placement) with two additional AP X-ray images capturing all the tools at once.
- Add a feature that allows the System to be used in an offline mode so that newly acquired X-ray images aren’t input and analyzed by the VUZE System.
- Generate cross-sections in the background. If generation fails, the software will suggest acquiring images from different C-arm angles, in advance. If the generation is successful, the user can then view the generated cross-sections within the software by pressing “Generate Cross-Sections”.
- Addition of a system verification that alerts the user when the tool trajectory changes significantly from what was previously accepted.
- Addition of an optional Bluetooth foot pedal with associated Bluetooth dongle for the System as an input device that activates the default action from the GUI at the time of activation.
- Upgrade GPU model from RTX-2080 to RTX-3090 to support faster CT to X-ray registration.
- Addition of DVI galvanic Isolator and replace existing optical video cable with DVI cable.
- Minor graphical user interface improvements for usability (e.g., snap to tool, screenshot tool, magnification view, display incision site, C-arm angles display in title bar, always provide next image angle suggestions, text changes).
- Resolution of non-safety related software anomalies.

- The differences in technology do not raise different questions of safety or effectiveness and were evaluated through comprehensive bench verification and validation testing including a usability study. The results of testing provide assurance that the device is as safe and effective as the Predicate.

For a more detailed comparison refer to the Substantial Equivalence comparison table included below.

Performance Data:

There are no identified special controls or performance standards for this device.

The modified VUZE System was verified and validated in accordance with 21 CFR 820.30. The following tests assessed comprehensively the changes in the system and were completed to demonstrate substantial equivalence and that any technological differences do not raise new or different questions of safety and effectiveness. The device successfully completed all of the evaluations and testing shown below. The standards shown in the following section were used, where applicable, to conduct testing and evaluate results.

- Hardware component / assembly functional verification
- Software Verification / Validation at the unit, integration and system levels (full execution of all software-based testing from original 510(k) with protocol modifications where necessary to fully test changes)
- Electrical Safety and EMC
- Full system functional verification against inputs and specifications
- Simulated Use / Quantitative Accuracy
- Formative Usability Validation

As listed above, quantitative accuracy performance of the VUZE System was evaluated in comparison to its performance specifications and found to meet all specifications. The following tables present the results of this performance testing.

	Parameter			
CT Angle Settings	**Direction error [deg]**	**Tip deviation from GT trajectory [mm]**	**Predicted tip deviation from GT trajectory [mm]**	**Depth error [mm]**
VUZE System Recommended Angles	0.3094	0.2833	0.3572	0.8196
Minimal Angle Difference (worst case)	0.4537	0.4107	0.5199	1.0194
RMS specification limit	**≤3º**	**≤2 mm**	**≤2 mm**	**≤4 mm**
All results within RMS specification limit	**Pass**	**Pass**	**Pass**	**Pass**

Results of the Root Mean Square (RMS) analysis at Recommend and Minimal Angle Differences between X-ray Images

Parameter	Specification	Quantile	Test Result	Using VUZE System Recommended Angles		Using Minimal Angle Difference	
				Quantile Estimate	95% Conf. Limit of Quantile	Quantile Estimate	95% Conf. Limit of Quantile
Direction error [deg]	< 5.7°	95%	**Pass**	0.545	0.556	0.851	0.892
Tip deviation from GT trajectory [mm]	< 2 mm	95%	**Pass**	0.479	0.490	0.798	0.824
Predicted tip deviation from GT trajectory [mm]	< 2 mm	95%	**Pass**	0.615	0.627	0.995	1.035
Depth error [mm] Lower	> -6.5 mm	2.5%	**Pass**	-1.371	-1.424	-1.939	-2.053
Depth error [mm] Upper	< 6.5 mm	97.5%	**Pass**	1.920	1.976	2.394	2.580

Summary of results for all combinations of X-Ray machines and CT/CBCT data.

No animal or human clinical data were needed to demonstrate substantial equivalency.

The device has been designed and tested in conformance to the following voluntary recognized consensus standards and continues to comply in its modified form. Note: The standard set below represents the current versions of the standards for which the original version of the VUZE system declared conformity.

- ANSI / AAMI / IEC 60601-1: 2005 /(R)2012 +A1:2012 + A2:2021: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (FDA Recognition #19-46)
- IEC 60601-1-2:2020 Edition 4.1, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests (FDA Recognition #19-36).
- IEC 62304:2006/A1:2016, Medical Device Software – Software Lifecycle Processes (FDA Recognition #13-79)
- IEC 62366-1:2015 + AMD1:2020: Medical devices - Part 1: Application of usability engineering to medical devices (FDA Recognition #5-129)
- ISO 10993-1:2018: Biological evaluation of Medical Devices, Part 1: Evaluation and Testing within a Risk Management Process (FDA Recognition #2-258)
- IEC 60601-1-6:2013-10 Edition 3.1: Medical Electrical Equipment – Part 1-6: Collateral Standard – Usability (FDA Recognition #5-89)
- ISO 14971:2019 Medical Devices: Application of Risk Management to Medical Devices (FDA Recognition #5-125)
- ISO 15223:2021 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements (FDA Recognition #5-134)

- ISO 20417:2021 Medical devices – Information to be supplied by the manufacturer (FDA Recognition #5-135)
- NEMA PS 3.1 - 3.20 (2021) Digital Imaging and Communications in Medicine (DICOM) Set (FDA Recognition #12-342)
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems (FDA Recognition #14-499)
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Part 2: Lithium systems (FDA Recognition #19-33)
- UN/DOT 38.3 5th Edition, Amendment 1: Recommendations on the Transport of Dangerous Goods
- UL 2054 2nd Edition House and Commercial Batteries

Substantial Equivalence Comparison:

Device Characteristic	Modified VUZE System (Subject Device)	Original VUZE system (Predicate, K210830)	Conclusion
Intended Use	Intended as an imaging aid for interventional procedures to allow comparison of planned tool paths against actual tool placement	Intended as an imaging aid for interventional procedures to allow comparison of planned tool paths against actual tool placement	Identical to Predicate
Indications for Use	The VUZE System is intended to enable users to load pre-operative 3D images and planning data and register and overlay this data in real time with intra-operative 2D radiographic images of the same anatomy to support device guidance during interventional spinal procedures. The system also offers pre-operative surgical planning including implant sizing, entry location, and trajectory determination along with intra-operative guidance and tool trajectory / position confirmation.	The VUZE System is intended to enable users to load pre-operative 3D images and planning data and register and overlay this data in real time with intra-operative 2D radiographic images of the same anatomy to support device guidance during interventional spinal procedures. The system also offers pre-operative surgical planning including implant sizing, entry location, and trajectory determination along with intra-operative guidance and tool trajectory / position confirmation.	Identical to Predicate
Device Class	II	II	Identical to Predicate
Procodes	LLZ	LLZ	Identical to Predicate
Anatomy	Thoracic and Lumbar Spine	Thoracic and Lumbar Spine	Identical to Predicate
Surgical Access Type	Percutaneous	Percutaneous	Identical to Predicate
Patient Population	General Spine Surgery	General Spine Surgery	Identical to Predicate
Target User	Interventional Spine Surgeon	Interventional Spine Surgeon	Identical to Predicate

Device Characteristic	Modified VUZE System (Subject Device)	Original VUZE system (Predicate, K210830)	Conclusion
Environment	Surgical Suite	Surgical Suite	Identical to Predicate
Procedure Hardware Platform	Dedicated Workstation	Dedicated Workstation	Identical to Predicate
Planning Hardware Platform	Commercial PC meeting specific requirements and not contain external software	Planning was performed on dedicated workstation performing both planning and procedure functions.	Substantially equivalent to Predicate
Work-Flow	3D imaging, planning, 2D imaging, 3D to 2D co-registration, intervention, confirmation	3D imaging, planning, 2D imaging, 3D to 2D co-registration, intervention, confirmation	Identical to Predicate
3D Image Data Source	CT / CBCT	CT	Substantially equivalent to Predicate
Interoperative Image Co-Registration	3D image to X-ray using Digitally Reconstructed Radiographs (DRR's)	3D image to X-ray using Digitally Reconstructed Radiographs (DRR's)	Identical to Predicate
Tool Use	Free hand	Free Hand	Identical to Predicate

Conclusion:

The results of the comparison of the modified VUZE System to the predicate device, in conjunction with the successful performance testing data gathered and described above, shows the VUZE system has the same intended use, similar technological characteristics, and that the differences in technological characteristics do not raise different questions of safety and effectiveness. Therefore, it is concluded the VUZE System is substantially equivalent to the original VUZE system (K210830).