VUZE Medical Ltd.
% Clay Anselmo
Principal Quality and Regulatory Consultant
Shriner & Associates Inc.
429 Whitepine Creek Road
TROUT CREEK MT 59874

January 3, 2021

Re: K210830
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: November 18, 2021
Received: November 23, 2021

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 (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)*
K210830

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K210830

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. 13 Zarhin St. Ra'Anana 4366241, Israel
510(k) contact person	Clay Anselmo Principal Quality and Regulatory Consultant Shriner & Associates 429 Whitepine Creek Road Trout Creek, MT 59874 clay.anselmo@shrinerandassociates.com (303) 907-2955
Date prepared	16–March-2021

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:	Innova Vision Applications
510(k) number:	K092639

Reference Device

Trade names:	Renaissance
510(k) number:	K140167

Device Description:

The VUZE System (the “System”) enables 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. 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 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 main system components include:

- Workstation running the VUZE Planning and Procedure software (pre-installed)
- Housing for the workstation, with a front door for user access as well as a back service door
- 32” touchscreen
- Isolation transformer
- Internal video acquisition device (frame grabber)
- Wheeled cart on which the above-listed items are placed.

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 Innova Vision Application (a.k.a. TrackVision) K092639. A reference device, (Mazor Robotics Renaissance System K140167) was used to address minor technology differences between the VUZE System and the TrackVision device.

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 VUZE System device has the same intended use and similar indications for use as the Predicate device.
- The VUZE System device uses the same fundamental technology as the Predicate device and very similar detailed technological solutions as follows:
    - The VUZE System utilizes 3D imaging data of the patient's target anatomy and pre-operative surgical planning information registered against intra-operative 2D x-ray images to support the correct placement of interventional devices (trajectory and position).
    - This approach to presenting co-registered 3D and 2D imaging information for the purposes of aiding tool guidance and tool placement confirmation is the same as the predicated device.
- The minor differences between the VUZE System device and the Predicate do not raise new types of questions of safety or effectiveness.
    - The differences in technology do not raise different questions of safety or effectiveness and were evaluated through comprehensive bench and usability verification and validation testing. 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 VUZE System was verified and validated in accordance with 21 CFR 820.30. The following tests 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 and functional unit verification and validation
- Packaging / Transportation Validation
- Software Verification / Validation at the unit, integration and system levels
- IEC 60601-1 Basic Safety and Essential Performance
- IEC 60601-1-2 Electromagnetic Compatibility (EMC)
- Simulated Use / Quantitative Accuracy
- Qualitative Image Output Validation
- Summative Usability Validation

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:

- ANSI / AAMI / IEC 60601-1: 2005 /(R)2012 +A1:2012: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (FDA Recognition #19-4)

- IEC 60601-1-2: Edition 4.0, 2014-02 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests Sections 7, 8 professional healthcare facility environment (FDA Recognition #19-8).
- IEC 62304:2006/A1:2016, Medical Device Software – Software Lifecycle Processes (FDA Recognition #13-79)
- IEC 62366-1:2015: Medical devices - Part 1: Application of usability engineering to medical devices (FDA Recognition #5-114)
- IEC 62366-1-6:2013-10 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 15223:2016 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements (FDA Recognition #5-117)
- NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set (FDA Recognition #12-300)
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems (FDA Recognition #14-499)

Substantial Equivalence Comparison:

Device Characteristic	VUZE (Subject Device)	Innova Vision Applications (Predicate, K092639)	Renaissance (Reference Device, K140167)	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	N/A	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.	Innova Vision Applications software is intended to enable users to load 3D datasets and overlay and register in real time these 3D datasets with radioscopic or radiographic images of the same anatomy in order to support catheter/device guidance during interventional procedures.	N/A	Substantially Equivalent
Device Class	II	II	II	Identical to All
Procodes	LLZ	LLZ	OLO, HAW, LLC	Identical to Predicate

Device Characteristic	VUZE (Subject Device)	Innova Vision Applications (Predicate, K092639)	Renaissance (Reference Device, K140167)	Conclusion
Anatomy	Thoracic and Lumbar Spine	Not specific. Anywhere radiographic images of the anatomy are available.	Spine	Subset of Predicate, Identical to Reference Device; Substantially Equivalent
Surgical Access Type	Percutaneous	Percutaneous	Open and Perc.	Identical to Predicate
Patient Population	General Spine Surgery	All tool-based interventions, not limited to specific clinical indication	General Spine Surgery	Subset of Predicate; Substantially Equivalent
Target User	Interventional Spine Surgeon	Interventional Surgeons including Ortho and Spine surgeons	Interventional Spine / Orthopedic Surgeon	Subset of Predicate, Identical to Reference Device; Substantially Equivalent
Environment	Surgical Suite	Catheter Lab, Surgical Suite	Surgical Suite	Subset of Predicate; Substantially Equivalent
Hardware Platform	Dedicated Workstation	Dedicated Workstation	Proprietary HW platform	Identical to Predicate
Work-Flow	3D imaging, planning, 2D imaging, 3D to 2D co-registration, intervention, confirmation	3D imaging, planning, 3D & 2D imaging, 3D to 3D/2D co-registration, intervention, confirmation	3D imaging, planning, 2D imaging, 3D to 2D co-registration, intervention, confirmation	Subset of Predicate, Identical to Reference Device; Substantially Equivalent
3D Image Data Source	CT	Cone-Beam CT	CT	Substantially Equivalent
Interoperative Image Co-Registration	3D image to X-ray using Digitally Reconstructed Radiographs (DRR's)	3D Image to Fluoroscopy and / or X-ray using X-ray position data.	3D image to X-ray using DRR's	Subset of Predicate, Identical to Reference Device; Substantially Equivalent
Tool Use	Free hand	Free hand	Robotic Assistance	Identical to Predicate

Conclusion:

The VUZE System is substantially equivalent to the Innova Vision Applications (K092639).