July 9, 2026

Provect.AI
% Paul Dryden
Consultant
ProMedic Consulting, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K253899
Trade/Device Name: 3D-Anywhere
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 9, 2026
Received: June 9, 2026

Dear Paul Dryden:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K253899

Device Name
3D-Anywhere

Indications for Use *(Describe)*
The 3D-Anywhere software provides processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.

The 3D-Anywhere software provides processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.

It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast anatomical structures, such as bony anatomy, particularly for orthopedic applications.

It is not intended to replace diagnostic imaging modalities (e.g., C-arm, CT or MRI) and is not indicated for procedures involving low contrast tissue or liquid materials.

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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Date Prepared:	9-Jun-26
Sponsor:	Provect.AI 115 Lancewood Pl. Los Gatos, CA 95032 Tel: 469-850-2282
Sponsor Contact:	Dorian Averbuch - CEO
Submission Correspondent:	Paul Dryden ProMedic Consulting, LLC
Proprietary or Trade Name:	3D-Anywhere
Classification Name:	Medical image management and processing system
Product Code:	QIH
CFR	892.2050
Predicate Device:	K081672, Mazor Surgical Technologies, Ltd, C-InSight System
Classification Name:	Medical image management and processing system
Product Code:	LLZ
CFR	892.2050

Device Description
The 3D-Anywhere software provides processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.

3D Anywhere is software that runs on an IEC 60601-1 compliant computer with a built-in touch screen display. The system connects to a customer-provided medical-grade monitor and to a C-Arm via standard video output for integration. The computer is from ONYX Healthcare model ACCEL-VM1000 with a Magewell Pro Capture AIO video capture card.

The system supports exporting reconstructed 3D volumes in standard DICOM format, ensuring compatibility with PACS systems and third-party imaging software.

Indications for Use:
The 3D-Anywhere software provides processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.

The 3D-Anywhere software provides processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.

It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast anatomical structures, such as bony anatomy, particularly for orthopedic applications.

It is not intended to replace diagnostic imaging modalities (e.g., C-arm, CT or MRI) and is not indicated for procedures involving low contrast tissue or liquid materials.

Patient Population:
Adults

Environments of use:
It is intended for use in hospital/institutional settings.

Table of Comparison of Subject vs. Predicate

	Proposed Device 3D-Anywhere	Predicate Mazor C-Insight System	Comparison
K#	**K253899**	**K081672**	
Product Code	**QIH**	**LLZ**	Added due to AI enabled utility
CFR	**892.2050**	**892.2050**	
Indications for Use	The 3D-Anywhere software provides processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. The 3D-Anywhere software provides processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast anatomical structures, such as bony anatomy, particularly for orthopedic applications. It is not intended to replace diagnostic imaging modalities (e.g., C-arm, CT or MRI) and is not indicated for procedures involving low contrast tissue or liquid materials.	The C-InSight software provides processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications.	Similar
Target Population	Orthopedic patients	Orthopedic patients	
Environment of Use	Hospital setting (operating room)	Hospital setting (operating room)	
Orthopedic procedures	Yes Orthopedic procedures	Yes Not specified	Similar
Fundamental scientific technology	Converts 2D fluoroscopy images into a 3D volume.	Converts 2D fluoroscopy images into a 3D volume.	Similar
Software based on a PC	Yes	Yes	Similar
Accessory	Jig with targets (markers) used for registration – non-sterile placed in a sterile pouch for use	Belt with targets (markers) in single-use sterile sheath.	Similar

	Proposed Device 3D-Anywhere	Predicate Mazor C-Insight System	Comparison
Equipment Compatibility	Each C-Arm model is qualified during installation	Not listed	Similar
Imaging Modalities	Fluoro based imaging	CT and Fluoro based imaging	Similar
Computer specifications	PC Workstation	PC Workstation	Similar
Standards	IEC 60601-1 IEC 60601-1-2 IEC 62304 (replaced IEC 60601-1-4) ISO/IEC/IEEE 29148:2018 Human Factors Cybersecurity Image Quality testing Software Validations	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-4 & FDA Guidelines Image Quality testing Software Validation	Similar

Difference Between Subject and Predicate

The subject device (Provect.AI 3D-Anywhere System) and the predicate device (Mazor C-Insight System, cleared under K081672) share a similar intended use, product code (LLZ), device classification (21 CFR 892.2050 – Radiological Image Processing System), and fundamental operational principle of generating a volumetric 3D dataset from 2D fluoroscopic projections acquired intraoperatively. Both devices process sequences of fluoroscopy images obtained from standard mobile C-Arm systems to produce a 3D volumetric representation of high-contrast anatomical structures.

Both devices only provide 3D imaging from 2D X-Ray, so there is no planning, registration and navigation. Doctor may use the generated images as a reference during a procedure or store in a DICOM format and upload into any other software reading DICOM, such as 3rd party DICOM viewer or 3rd party navigation software

Any differences are limited to system configuration, accessory design, and implementation details. These differences do **not** alter the intended use, mode of operation, or raise new questions of safety or effectiveness.

Key differences include:

Feature	Subject Device – Provect.AI 3D-Anywhere	Predicate – Mazor C-Insight (K081672)	Comment
Reference Object for Pose Estimation	Rigid rectangular jig placed externally in a sterile bag and secured adjacent to the anatomical region of interest.	Sterile belt-style reference marker positioned around the anatomy of interest.	Same fundamental function (image-based pose estimation). Form factor change does not alter imaging principle or user interaction steps.
Disposable Components	No disposable components; the jig is reusable and sterile-barrier protected.	Includes a single-use sterile sheath and belt accessory.	Eliminates special disposable use without affecting safety or workflow. No new materials contact the patient.
Algorithmic Implementation	Tomographic reconstruction using geometric estimation based on Rectangular Jig coordinate system	Tomographic reconstruction using geometric estimation based on belt coordinate system.	Same scientific principle. Differences are implementation-level and validated through performance testing.
Hardware Platform	Runs on a modern workstation-based PC.	Runs on a workstation-based PC.	Same. Improved performance only; does not change feature set, architecture category, or user workflow.

Non-clinical Testing

Non-clinical testing was performed to verify and validate the 3D-Anywhere system against its design requirements and intended use. The testing included software verification, hardware verification,

cybersecurity testing, penetration testing, imaging performance testing, workflow validation, and physician image-review validation.

Software testing included static analysis, code review, unit and integration testing, system-level workflow testing, regression testing, stress testing, and exploratory testing. Hardware testing verified the integrated computing platform, image capture hardware, fluoroscopic jig, display interfaces, and related system components.

Imaging performance was evaluated using a combination of phantom testing, simulated datasets generated from reference CT images, and cadaveric acquisitions obtained under representative imaging conditions. The evaluated performance characteristics included geometric accuracy, spatial resolution, image noise, bone contrast and visibility, and robustness to acquisition and patient-size variability. Testing included assessment of reconstructed 3D volume accuracy, isotropic resolution in multiple anatomical planes, noise behavior using volumetric noise analysis, and bone-to-background contrast across phantom, simulated, and cadaveric datasets. The imaging performance results met the predefined acceptance criteria and supported the ability of the system to generate CT-like 3D images suitable for the intended orthopedic use environment.

Cybersecurity testing verified implementation of access control, authentication, integrity protection, data protection, malware protection, vulnerability management, network isolation, and event logging. Penetration testing was also performed to assess the system within the defined cybersecurity test scope. The results confirmed that cybersecurity controls were implemented as intended, and any identified findings were resolved or assessed as acceptable residual risk.

Workflow validation confirmed that intended users could complete representative setup, acquisition, reconstruction, and image-review workflows using the 3D-Anywhere system. Physician image-review validation confirmed that the reconstructed 3D images provided CT-like visualization suitable for the intended orthopedic use environment.

The results of non-clinical testing support that the 3D-Anywhere system meets its specified performance, safety, workflow, and cybersecurity requirements and is suitable for its intended use.

Clinical Testing

Not performed

Substantial Equivalence Discussion

As discussed above, the differences between the subject device and predicate do not raise different risk concerns compared to the predicate.

Substantial Equivalence Conclusion

The sponsor has demonstrated through testing and comparison that the subject device is substantially equivalent to the predicate.