PrecisionOS Technology Inc.
℅ Danny P. Goel, M.D.
CEO & Cofounder
500-319 West Hastings Street
Vancouver, British Columbia V6B 1H6
CANADA

November 10, 2021

Re: K210344
Trade/Device Name: inVisionOS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: Septeber 22, 2021
Received: October 6, 2021

Dear Dr. Goel:

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)*
K210344

Device Name
inVisionOS

Indications for Use *(Describe)*
inVisionOS is a software-based medical image viewing system intended for use as a software interface for the pre-operative evaluation of surgical treatment options of bone pathologies imaged using CT scans.

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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| VOLUME # | TITLE | |
|---|---|---|
| 5 | 510(K) SUMMARY | K210344 |

**510(k) Applicant:** PrecisionOS Technology Inc.
500 - 319 West Hastings Street
Vancouver, British Columbia
Canada V6B 1H6

**Contact Person:** Danny Goel
CEO & Co-founder
Phone: +1 (877) 673-0176
danny@precisionostech.com

**Date Prepared:** January 27, 2021

**Device Trade Name:** inVisionOS™

**Common Name:** System, Image Processing, Radiological

**Classification Name:** Picture Archiving and Communications System

**Regulation Number:** 21 CFR 892.2050

**Product Code:** LLZ

**Classification:** II

**Panel:** Radiology

**Primary Predicate Device:** K201465 – SuRgical Planner (SRP) BrainStorm

**Predicate Device:** K182464 – PeekMed

**Device Description:** inVisionOS is a software-based pre-surgical planning system with a virtual reality (VR) headset. It is intended as pre-operative planning software for the evaluation of orthopedic surgical treatment options. The inVisionOS software displays virtual reality 3D models of patient data by uploading and converting Computed Tomography (CT) data into a 3-Dimensional (3D) format to be used with a virtual reality (VR) headset. It provides the user with the ability to manipulate the 3D model from multiple points of view through translation, rotation, and scaling. The user can position the Slice Plane Tool in the sagittal, coronal, axial, and oblique planes over the 3D model. This permits the user to view a CT-based 2D image at intersecting points along the plane. The inVisionOS software with a VR headset

and controllers is not intended for use during surgery. The inVisionOS software is not intended to be used for diagnosis.

**Indications for Use:** inVisionOS is a software-based medical image viewing system intended for use as a software interface for the pre-operative evaluation of surgical treatment options of bone pathologies imaged using CT scans.

**Substantial Equivalence:** The indicated use, design, and technological characteristics for inVisionOS are the same as the predicate devices: software-based 3D medical image viewing system for the pre-operative evaluation of surgical treatment options imaged using CT scans. The indicated use for inVisionOS is consistent with the indicated use of the primary predicate device, with the exception of the field of intended use. The indicated use for inVisionOS is consistent with the indicated use of the secondary predicate device and is used to view the same field of intended use. Software verification and usability validation demonstrates that inVisionOS may be used for the same indicated uses as the predicate devices and any technological differences do not raise any safety or effectiveness concerns.

**Performance Testing:** Verification and validation activities, driven by risk analysis guided by ISO 14971:2007, were conducted and documentation is provided. These activities included software verification and validation, unit testing, cybersecurity, image accuracy and system testing. Usability testing was conducted in a simulated-use environment by appropriately trained health care providers. All testing activities demonstrated that the device met all design requirements and intended use, and that it is both safe and effective. No animal or clinical testing was required to support safety and effectiveness of the subject device.

The software for inVisionOS was deemed to be “moderate” level of concern since a failure or latent flaw in the software could indirectly result in minor injury to the patient or user.

**Conclusion:** The design and development of inVisionOS according to 21 CFR Part 820.30 Design Controls and FDA’s Guidance for Industry and FDA Staff “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” provide objective evidence that inVisionOS is as safe, effective and performs, at least, as well as the predicate devices.

Moreover, based on the shared intended use and technological characteristics, inVisionOS is substantially equivalent to the predicate devices. Though there are slight differences in the technological characteristics between inVisionOS and the predicate devices, these differences do not introduce additional questions concerning the safety and/or effectiveness of inVisionOS. The verification, validation and usability studies conducted with inVisionOS provide objective evidence of its safety and effectiveness for its indicated use.