DeepLook Inc.
% Mr. Carl Alletto
Regulatory Consultant
OTech Inc.
8317 Belew Drive
MCKINNEY TX 75071

April 9, 2021

Re: K202084
Trade/Device Name: DeepLook PRECISE
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 5, 2021
Received: March 15, 2021

Dear Mr. Alletto:

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,

Michael D. O'Hara 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)*
K202084

Device Name
DeepLook PRECISE

Indications for Use *(Describe)*
DeepLook PRECISE is a software device that is integrated into medical Image Viewers and PACS workstations to assist trained professionals in measuring dimensions of objects within a region of interest (ROI) that is identified by the user in DICOM images. The generated information consists of an estimated greatest long-axis and greatest short-axis dimensions, area, volume, and margin of the objects. For illustration purposes, DeepLook PRECISE can optionally provide a colorization of the interior area defined by a margin. DeepLook PRECISE does not make clinical decisions nor is a decision-support tool. The information provided by the software is an initial estimate and must not be used in isolation when making patient management decisions.
Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using and FDA cleared monitor that offers at least 5 Mega-pixel resolutions and meets other technical specifications reviewed and accepted by FDA. Typical users of this system are trained physicians and radiologists.
DeepLook PRECISE, is not intended for use on mobile devices.

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 of Safety

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared: March 29, 2011

510(k) Number: K202084

I. SUBMITTER

DeepLook Inc.
1220 Burton Street
Silver Spring, MD 20910
TEL: 202.306.0808
Email: Steve.schwadron@DeepLookMedical.com

Contact Person: Mr. Steven Schwadron, Chief Operating Officer

II. DEVICE

Name of Device:	DeepLook PRECISE
Common or Usual Name:	Picture Archive and Communications System
Regulation Name:	System, Image Processing, Radiological
Regulation:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Class:	II

III. PREDICATE DEVICE

Device Classification Name	System, Image Processing, Radiological
510(K) Number	K191530
Device Name	StoneChecker
Applicant	Imaging Biometrics, LLC 13416 Watertown Plank Road, Suite 260 Elm Grove, WI 53122
Regulation Number	892.2050
Regulation Medical Specialty	Radiology

IV. DEVICE DESCRIPTION

DeepLook PRECISE, is a software application that works embedded in PACS/EIS or OEM viewers. It provides automated measurement, replacing manual digital calipers currently used to measure objects in digital medical imaging.

It is a Windows OS service that uses XML messaging to receive Commands from the viewer application; it processes results independently and returns requested data to the viewer application via the same XML messaging. The software is not compiled within the viewer's application. As a result, integration is simplified and limited to establishing XML protocols for reciprocal Commands.

DeepLook PRECISE can operate on an individual workstation, local servers or in Cloud-based applications.

The software uses patented shape-recognition processes to analyze Regions of Interest (ROIs) identified by a trained medical user (i.e., imaging technologist, radiologist, physician or researcher). When requesting a measurement, the user triggers a set of XML Commands via the viewer interface. The primary Command is a request for a

measurement of an object located within an ROI designated by the user using a mouse to click on the location of a suspected object.

DeepLook receives the Command, processes the area within the ROI and assembles the candidate shapes (and all relevant metrics) and returns a full set of displays (bundled and prioritized) that depict the possible boundaries of the object. To facilitate initial viewing, DeepLook PRECISE designates a default shape; this shape is recommended as the best depiction of the targeted margin of the object. The selection of the default shape from the display stack is determined by a set of deterministic algorithms that sort for the best candidate shape based on shape recognition ratios developed by DeepLook. Based on training and professional skill, a user can use simple keystroke Commands or a track ball or mouse wheel to move through the entire stack of alternative margins (shapes) and select the one that they conclude best represents the targeted object.

Once a candidate shape has been chosen, the user has the option to extend or contract any specific section of the margin in order to include or exclude a feature they deem relevant. Any alteration of the contours of the displayed margin will recalculate the overall measurement metrics (i.e., calculate two new axis measurements, and the area and estimated volume). The results will instantly appear with the modified margin.

The Commands to accept the default shape-display or select alternative shape-displays and any modification of selected shape-displays are all executed using keystroke or track ball functions that are initiated by the user through the viewer interface. Each resulting shape includes all relevant measurement metrics when displayed, allowing for quick comparison and selection.

For illustrative purposes, the software offers a colorization display of the internal shapes within a candidate margin: each of the shapes within the outer margin of a targeted object or anatomical structure is assigned a calibrated color. This is offered solely to assist the user in distinguishing the shape components when making a final selection. The colorization is not a decision-support or diagnostic tool.

The measurements and graphical display can be saved. Depending on the viewer configuration, this data can be saved 1) to the hard drive of the workstation; 2) to a server on the premises or in the Cloud; 3) in a structured report; or 4) configured to comply with DICOM data fields and saved to the PACS. The location of the saved display will be determined by the viewer manufacturer and/or the user.

The displays of DeepLook PRECISE described above offer the user consistent measurement of each shape. The modification functions provide the user with maximum flexibility to adjust the default shape or any other shapes in the display stack. The user can also decline all suggested shapes generated by DeepLook PRECISE and use standard mouse-operated digital calipers to measure the target object.

The final configuration of the user interface (i.e., keystrokes, track ball and hot-key Commands) will be determined by each vendor that integrates DeepLook PRECISE. To assist the vendor during integration, each XML Command and display option is illustrated separately in this manual. This provides the integrator with the option of selecting some or all the functions and to determine the best Commands to incorporate, consistent with its own user interface.

DeepLook PRECISE is stand-alone Windows OS service designed to permit maintenance and performance improvements *without* the need to modify established XML protocols used to send and receive Commands. This eliminates the need for additional vendor integration/interactions when patches and/or updates are required to DeepLook PRECISE's Windows OS service.

V. INDICATIONS FOR USE

DeepLook PRECISE is a software device that is integrated into medical Image Viewers and PACS workstations to assist trained professionals in measuring dimensions of objects within a region of interest (ROI) that is identified by the user in DICOM

images. The generated information consists of an estimated greatest long-axis and greatest short-axis dimensions, area, volume, and margin of the objects. For illustration purposes, DeepLook PRECISE can optionally provide a colorization of the interior area defined by a margin. DeepLook PRECISE does not make clinical decisions nor is a decision-support tool. The information provided by the software is an initial estimate and must not be used in isolation when making patient management decisions.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using and FDA cleared monitor that offers at least 5 Mega-pixel resolutions and meets other technical specifications reviewed and accepted by FDA. Typical users of this system are trained physicians and radiologists. DeepLook PRECISE, is not intended for use on mobile devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The following is a comparison of the subject device and the predicate device:

Ref #	Technical Characteristic	Subject Device – DeepLook PRECISE	Predicate – StoneChecker K191530	Difference/Comments
Indications for Use				
1	Statement references a software only device.	Yes	Yes	No significant difference
2	Statement references DICOM Standard.	Yes	Yes	No significant difference
3	Statement references the display / view of medical images.	Yes	Yes	No significant difference
4	Statement references the output of information	Yes	Yes	No significant difference
5	Statement references the user selection of ROIs	Yes	Yes	No significant difference
6	Statement references providing the clinician with information about an ROI.	Yes	Yes	No significant difference
7	Statement references providing the user with information related to kidney stones.	No	Yes	Yes, there is a difference. The subject device can measure any object within a ROI identified by the User and is not intended specifically for kidney stones. The device Intended Use is clearly detailed in the device labeling and does not modify existing risks or raise any new potential safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
8	Intended Users	Trained physicians, radiologists.	Trained physicians, radiologists.	No Difference
9	Target population	No restrictions	Patients diagnosed with	Yes, there is a difference. There are no restrictions with the subject

Ref #	Technical Characteristic	Subject Device – DeepLook PRECISE	Predicate – StoneChecker K191530	Difference/Comments
			kidney stones that require medical intervention.	device on the target population and is not intended for a specific population as detailed in the labeling. The subject device is applied to DICOM Images and not specific target populations. Target populations are the responsibility of the modalities. This difference does not modify existing risks or raise any new potential safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
10	Anatomical sites	No restrictions	Kidneys, ureters, and bladder (KUB)	Yes, there is a difference. No anatomical sites are specified in the subject device labeling. This does not modify existing risks or raise any new potential safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
11	Where used	No restrictions	No restrictions	No significant difference.
Design				
1	Software device that operates on off-the-shelf hardware.	Yes	Yes	No significant difference.
2	Software device uses a standard windowing user interface.	Yes	Yes	No significant difference.
3	Software device uses software algorithms for image post processing analysis.	Yes	Yes	No significant difference. The subject device software is used for measurement.
4	Conforms to DICOM standards (PS 3.10)	Yes	Yes	No significant difference
Features and Capabilities				
5	Data loading of CT image series using DICOM standard	Yes	Yes	DeepLook PRECISE can handle any DICOM image and does not restrictive to a specific modality.
6	2D image review	Yes	Yes	No significant difference
7	Image navigation tools (pan, zoom, scroll, window/level)	No	Yes	DeepLook PRECISE functions are measurement tools. Other image management functions are left to the PACS OEM software which is not part of DeepLook PRECISE. Therefore, it is our determination that this difference does not have a negative impact on safety or efficacy and there are no new

Ref #	Technical Characteristic	Subject Device – DeepLook PRECISE	Predicate – StoneChecker K191530	Difference/Comments
				potential or increased safety risks concerning these differences.
8	Measurement tools (ruler, ROI)	Yes	Yes	No significant difference
9	Size calculations (area, volume)	Yes	Yes	No significant difference
10	Statistical calculations	No	Mean, standard deviation (SD), mean of positive pixels, skewness, kurtosis, entropy	Yes, there is a difference. DeepLook PRECISE functions are measurement tool related. The generated information consists of an initial estimated greatest long-axis and greatest short-axis dimensions, area, volume, and positions of objects. Other image management functions are left to the PACS OEM software which is not part of DeepLook PRECISE. This does not modify existing risks or raise any new potential safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
11	CT texture analysis calculations	No	Yes	Yes. There is a difference. DeepLook PRECISE functions are measurement tools and is integrated with an OEM PACS system which is not part of DeepLook PRECISE. The subject device is applied to any DICOM image and is not modality specific. This is explained in the device Manual. This difference does not modify existing risks or raise any new potential safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
12	Display output of measurements and information.	Yes	Yes	No significant difference
13	Report generation	No	Excel	Yes, there is a difference. Reports are not generated by DeepLook PRECISE but are generated by the OEM PACS application which is not part of the subject device. This difference does not modify existing risks or raise any new potential safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
Physical Characteristics				

Ref #	Technical Characteristic	Subject Device – DeepLook PRECISE	Predicate – StoneChecker K191530	Difference/Comments
14	Post-processing (non-real-time, non-contacting, non-life supporting and not life sustaining).	Yes	Yes	No significant difference

VII. PERFORMANCE DATA

Nonclinical Testing:

The subject device has been assessed and tested at the factory to assess all functions and has passed all predetermined testing criteria.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

The following Standards were used to test the system and DeepLook PRECISE, has met the applicable requirements:

- ISO 14971 Third Edition 2019-12 Medical devices – Application of risk management to medical devices: FDA FR Recognition 5-125.
- NEMA PS 3.1 - 3.20 (2016, Digital Imaging and Communications in Medicine (DICOM) Set, FDA FR Recognition # 12-300.
- IEC 62304:2006/A1:2016, Medical device software - Software life cycle processes, FDA FR Recognition # 13-79.
- FDA Guidance on Cyber Security: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Document Issued on: October 2, 2014.
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.

Conclusion:

The 510(k) Pre-Market Notification for DeepLook PRECISE, software device contains adequate information, data, and nonclinical test results to enable FDA -CDRH to determine substantial equivalence to the predicate device.

The subject device will be manufactured in accordance with the voluntary standards listed in the voluntary standard survey. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, DeepLook PRECISE, is substantially equivalent to the predicate device.