



Certis Health  
% Mark Job  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1394 25th Street, NW  
Buffalo, Minnesota 55313

February 14, 2019

Re: K190074

Trade/Device Name: Presero 3D Scanning System  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: Class II  
Product Code: LLZ, FXN  
Dated: January 14, 2019  
Received: January 16, 2019

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R. Ogden -S  
Digitally signed by Neil  
R Ogden -S  
Date: 2019.02.14  
14:34:08 -05'00'

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K190074

Device Name

Presero 3D Scanning System

Indications for Use (Describe)

The Presero 3D Scanning System is an imaging tool that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a 3D imaging device. It is indicated for the use of capturing visual images to measure the diameter, surface area, perimeter and volume of wounds. The Presero 3D Scanning System is designed for use by health care professionals and is intended to assist the healthcare professional who is responsible for making all final patient management decisions.

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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**Traditional 510(k) for Presero® 3D Scanning System**
**Section 5. 510(k) SUMMARY**
**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

<b>Submitter's Name:</b>	Certis Health®
<b>Submitter's Address:</b>	3630 Park Central Boulevard North Pompano Beach, FL 33064
<b>Submitter's Phone No:</b>	954-628-5908
<b>Submitter's Fax No.</b>	954-206-1692
<b>Regulatory Contact:</b>	Charnelle Thomas Regulatory Consultant 404-360-6188  <b>Mailing address for regulatory correspondence:</b> 159 Lake Reserve Way Canton, GA 30115
<b>Date of Preparation:</b>	February 13, 2019
<b>Device Information:</b>	
<b>Trade Name:</b>	Presero™ 3D Scanning System
<b>Common Name:</b>	Imaging Software System
<b>Classification Name:</b>	Picture archiving and communications system
<b>Review Category:</b>	System, image processing, radiological 21 CFR 892.2050 (LLZ), 21 CFR 878.4160 FXN
<b>Classification Panel:</b>	Radiological
<b>Regulatory Class:</b>	Class II
<b>Product Code:</b>	LLZ, FXN
<b>Legally marketed device to which equivalency is claimed:</b>	EchoPixel True 3D Viewer (K142107)

**Traditional 510(k) for Presero® 3D Scanning System**

<p><b>Description of the device:</b></p>	<p>The Presero 3D Scanning System is a tablet-based system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a 3D imaging device.</p> <p>The Presero 3D Scanning System, does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.</p> <p>The Presero 3D Scanning System is comprised of a commercial off the shelf 3D camera fitted on a commercial off the shelf tablet, equipped with a proprietary software application that enables a health care professional to visualize and interact with 3D wound images, via a pen-like stylus, to assist in clinical decision making. The complete system (tablet, camera and software) integrates with a cloud back-end system. The cloud back-end system stores all patient data, operator details and other information allowing 2-way synchronization between the Presero 3D Scanning System and the cloud with the ability to fully support multiple systems within a single clinical facility.</p>
<p><b>Indications for Use:</b></p>	<p>The Presero 3D Scanning System is an imaging tool that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a 3D imaging device. It is indicated for the use of capturing visual images to measure the diameter, surface area, perimeter and volume of wounds. The Presero 3D Scanning System is designed for use by health care professionals and is intended to assist the healthcare professional who is responsible for making all final patient management decisions.</p>

**Traditional 510(k) for Presero® 3D Scanning System**

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION** (Continued)

<p><b>Summary of technological characteristics compared to the predicate device:</b></p>	<p>The Presero® 3D Scanning System is similar to the “primary” predicate device, the EchoPixel True 3D Viewer (K142107) with regard to its intended use and core technological characteristics with the exception of the source used to obtain the 3D images and the type of images evaluated by health care professionals in final patient management decisions. The Woundvision® Wound Measuring and Monitoring device (K131596) is a “reference” device and has an intended use and core technology that is also substantially equivalent to the Presero® 3D Scanning System.</p>		
<p><b>Substantial Equivalence:</b></p>	<p align="center"><b>Primary Predicate Echo Pixel True 3D Viewer (K141207)</b></p>	<p align="center"><b>Reference Device Wondvision Wound Measuring &amp; Monitoring Device (K131596)</b></p>	<p align="center"><b>Subject Device Presero 3D Scanning System</b></p>
<p><b>Intended Use:</b></p>	<p>Intended as a medical diagnostic imaging system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from CT or MR imaging devices. It is also intended as pre-operative software for simulating / evaluating surgical treatment options. The True 3D Viewer is designed for use by health care professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.</p>	<p>The Scout is a combination digital camera and long-wave infrared camera. The digital camera is indicated for the use of capturing visual images to measure the diameter, surface area, and perimeter of a part of the body or two body surfaces. The long-wave infrared camera is indicated for the use of capturing thermal images to measure the thermal intensity data of a part of the body or two body surfaces: Both components of the Scout are non-contact with respect to the patient and provide an adjunctive tool to help a trained and qualified health care professional</p>	<p>The Presero 3D Scanning System is a medical diagnostic imaging system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a 3D imaging device. It is also intended as a pre-operative software for evaluating treatment options. The Presero 3D Scanning System is designed for use by health care professionals and is intended to assist the healthcare professional who is responsible for making all final patient management decisions.</p>

**Traditional 510(k) for Presero® 3D Scanning System**

		measure and record external wound and body surface data.	
	<b>Primary Predicate Echo Pixel True 3D Viewer (K142107)</b>	<b>Reference Device Woundvision Wound Measuring &amp; Monitoring Device (K131596)</b>	<b>Subject Device Presero 3D Scanning System</b>
<b>Intended Users:</b>	Health Care Professionals	Health Care Professionals	Health Care Professionals
<b>Intended Environment for Care:</b>	Healthcare Facilities such as hospitals and clinics	Healthcare Facilities such as hospitals and clinics	Healthcare Facilities such as hospitals and clinics
	Class II	Class I	Class II
	21 CFR 892.2050; LLZ	21 CFR 878.4160; FXN	21 CFR 892.2050; LLZ
<b>Image Analysis Feature:</b>	Image analysis features: interactive manipulation, tag, annotate, measure, segment	measure	Image analysis features: interactive manipulation, tag, annotate, measure, segment
<b>Computer Platform: (minimum platform)</b>	HP Z440 Workstation	Minimum requirement: Intel Core i5 3rd generation (or equivalent) or better	Microsoft Surface Pro 4 or Microsoft New Surface Pro
<b>System RAM:</b>	8 GB of system memory; NVidia Quadro Graphics Processing Unit (GPU) with 4GB of video memory	4GB or greater	8 GB of system memory
<b>Operating System:</b>	Windows 7 or 10 (64bit)	Windows 7 SP1 or later	Windows 10 (64bit)
<b>Image Acquisition:</b>	CT and MR DICOM Images	Scout imaging device	Intel RealSense 3D camera
<b>Performance Data:</b>	<p>Every specification of the Presero® 3D Scanning Software has been validated according to the company's documented development and test procedures. The verification and validation testing conducted included testing to the following applicable standards:</p> <ul style="list-style-type: none"> <li>• ISO/IEC/IEEE 29148:2011, Systems and software Engineering — Life Cycle Processes — Requirements Engineering</li> <li>• ISO/IEC/IEEE 24765:2010 - Systems and software engineering –</li> </ul>		

**Traditional 510(k) for Presero® 3D Scanning System**

	<p>Vocabulary</p> <ul style="list-style-type: none"> <li>• IEC 62304:2006+AMD1:2015 CSV, Medical Device software – software Life-Cycle Processes</li> <li>• NEMA PS 3.1 - 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM) Set PS 3.1</li> <li>• 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 disturbances - Requirements and tests</li> <li>• ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)</li> </ul> <p>Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, which included testing that fulfills the requirements of FDA "Guidance on Software Contained in Medical Devices". Potential risks were analyzed and satisfactorily mitigated in the device design. Verification and validation was performed on qualified device as well as in simulated use conditions</p>
<b>Conclusions:</b>	<p>The Presero® 3D Scanning System is substantially equivalent to the primary predicate device with regards to intended use and technological characteristics. It is also substantially equivalent to the reference device. Results of performance testing demonstrated that the device met the design requirements and as well as the user needs.</p>