March 13, 2026

Good Methods Global Inc.
% Sakthileela Nagaiyan
Team Lead (USFDA Compliance - Medical Devices)
I3cglobal Reghelps Pvt Ltd
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Shankaraa, Kanakapura Road, Doddakallasandra
BANGALORE, KARNATAKA 560062
INDIA

Re: K253111
Trade/Device Name: Aeka Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 11, 2026
Received: February 11, 2026

Dear Sakthileela Nagaiyan:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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)*
K253111

Device Name
Aeka Imaging

Indications for Use *(Describe)*
Aeka Imaging is a clinical software application that provides a web-based interface for image acquisition and image management in the field of Dentistry and operated by dental professionals who are responsible for providing dental care.

Aeka Imaging receives patient's dental images from various dental acquisition devices (for eg. radiographic devices, digital image/video capture devices, generic devices such as scanners). Also, the previously acquired images or volumes can be selected for upload directly from the user's computer.

The software is intended to acquire, display, process edit (rotate, flip, resize, change brightness/contrast/gamma), annotate, review, store, print and distribute patient images using standard PC hardware.

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.

510(k) SUMMARY (K253111)

[AS REQUIRED BY 21CFR807.92]

I. SUBMITTER

510(k) Owner's Name	:	GOOD METHODS GLOBAL INC
Address	:	2954 Mallory Cir Ste 209 Celebration, FL 34747-1822, United States of America.
Telephone	:	+1-2816785215
Contact person	:	Arjun Satheesh
Designation	:	Head of Operations
Contact Number	:	+91 8056087271
Contact Email	:	arjun@carestack.com
Date of Summary Prepared	:	March 11, 2026

II. DEVICE

Trade Name	:	Aeka Imaging
Device Common Name	:	Dental Imaging Software
Device Classification Name	:	Medical image management and processing system
Class	:	Class II
Regulation Number	:	21 CFR 892.2050
Product Code	:	LLZ

III. PREDICATE DEVICE

Predicate Device Name	:	SOTA Cloud Imaging
510(k) Number	:	K210682
Device Classification Name	:	Medical image management and processing system
Class	:	Class II
Regulation Number	:	21 CFR 892.2050
Product Code	:	LLZ

IV. DEVICE DESCRIPTION

Aeka Imaging is a clinical software application designed to provide a web-based interface for image acquisition and management in the field of dentistry. Operated by dental professionals responsible for delivering dental care, it supports receiving images and data from digital x-ray sensors, radiographic devices, digital video capture devices, and generic imaging devices such as phosphor plate scanners via Twain integration or Direct integration. Users can also upload previously acquired images directly from their computers. The software allows for acquiring, displaying, processing, editing (e.g., rotating, flipping, resizing, adjusting brightness/contrast), annotating, reviewing, storing, printing, and distributing patient images using standard PC hardware.

Aeka Imaging has 5 interfaces designed for optimal functionality, which is:

1) Home Page

2) Patient Overview

3) Settings Page

4) Layouts Page

5) Acquisition page

Aeka hub should be installed in all ima ge acquiring workstations. This hub is for facilitating image acquisitions and it is also mandatory to have the device drivers of the Imaging devices installed in these systems as a prerequisite.

Aeka Imaging also provides a tool for measuring the distance between two endpoints in an image, the value for this measurement tool primarily depends on the value configured by the user. The user set this initial value on the Calibrate option that they have in the Image Editor screen, hence Aeka doesn't auto calculate a measurement.

Aeka Imaging has supports image acquisition with the below image types:-

1) X-Ray Images
2) IO Camera
3) Panoramic Images

And Aeka imaging has two types of integration

1) Twain integration – Aeka supports any Imaging device that has a twain driver.

2) Direct Integration – Aeka Imaging has 23 direct integration and the list includes **Apixia, Athlos, Dental Focus PS-2, e2v, EzSensor, FireCR Dental, Flatbed Scanner, Gendex Scanners, Gendex Sensors, Hamamatsu, iCRco, iRay, Jazz, Nical, Optime, Planmeca IO, Progeny,**

Rayence, ScanX, ScanX Pro, Sopix, Vidar, VistaRay. This means for all these imaging devices Aeka has Software Development Kit which allows to have a much seamless integration than a conventional twain integration.

Aeka Imaging integrates with other Practice Management Softwares, enabling users to access Aeka Imaging directly from the PMS. When navigating to Aeka Imaging from the PMS, the patient's context is automatically loaded, with the details transferred from the PMS. The patient information in Aeka Imaging is sourced from the PMS, hence these data solely depend on the PMS data.

V. INDICATIONS FOR USE

Aeka Imaging is a clinical software application that provides a web-based interface for image acquisition and image management in the field of Dentistry and operated by dental professionals who are responsible for providing dental care

Aeka Imaging receives patient’s dental images from various dental acquisition devices (for eg. radiographic devices, digital image/video capture devices, generic devices such as scanners). Also, the previously acquired images or volumes can be selected for upload directly from the user's computer.

The software is intended to acquire, display, process edit (rotate, flip, resize, change brightness/contrast/gamma), annotate, review, store, print and distribute patient images using standard PC hardware.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: General Comparison

Sl. No	Features compared	Proposed Device	Predicate Device	Result
General Information				
1.	510(k) Number	K253111	K210682	-
2.	Manufacturer	Good Methods Global Inc.	Sota Precision Optics, Inc. dba SOTA Imaging	-
3.	Classification	Class II	Class II	Same
4.	Product Code	LLZ	LLZ	Same
5.	Indication For Use	Aeka Imaging is a clinical software application that provides a web-based interface for image acquisition and image management in the field of Dentistry and operated by dental professionals who are responsible for providing dental care. Aeka Imaging receives patient's dental images from various dental acquisition devices (for eg. radiographic devices, digital image/video capture devices, generic devices such as scanners). Also, the previously acquired images or volumes can be selected for upload directly from the user's computer. The software is intended to acquire, display, process edit (rotate, flip,resize, change brightness/contrast/gamma), annotate, review, store, print and distribute patient images using standard PC hardware.	SOTA Cloud Imaging is indicated for use as a clinical software application that receives images and data from Clio or Clio Prime sensors and various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, SOTA Cloud Imaging enables the storage of clinical notes and clinical exam data. SOTA Cloud Imaging is intended to acquire, display, process, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware. SOTA Cloud Imaging is also intended for use for diagnostic and non-diagnostic purposes in the field of Dentistry by dental professionals who are responsible for providing dental care.	Similar
5.	Prescription Use or OTC Use	Prescription Use	Prescription Use	Same
6.	Operating System	Windows 11, macOS 15 Sequoia or Higher	Microsoft Windows	Same
7.	DICOM-compliant	Yes	Yes	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
8.	List of Modality support	- Intraoral Radiographic Devices (Digital X-ray sensors, Flat bed scanners). - Intraoral Camera, Intraoral video capture devices. - Panoramic X-ray devices.	Intraoral X-ray sensors, Intraoral cameras radiographic devices, flatbed scanners, digital cameras, and generic image devices,	Same
9.	Web Browsers Supported	Google Chrome (Chromium based Browsers)	Modern web-browser using HTML5, CSS3, and JavaScript	Similar
10.	Mobile Device Support	No	No	Same
11.	Multi planar reconstruction (MPR) and 3D image rendering	No	No	Same
12.	Image format	Saved as PNG File Format (.png extension) and can be exported as DICOM, JPEG, PNG, TIFF, PDF	Saved using lossless compression, and can be exported as DICOM, PNG, JPEG, or PDF files.	Similar
13.	Image file import/export	Yes	Yes	Same
14.	Image Visualization	Yes	Yes	Same
15.	Image zoom in/out	Yes	Yes	Same
16.	Storage capacity	Cloud Storage: Scalable, based on patient image volume Local Storage: Minimum of 500 MB is prescribed as a system requirement (to be available at the workstations where acquisitions are handled)	NA	-
17.	Is software integrated with AI/ML?	No	No	Same
		- Acquiring images from standard dental imaging devices.(for eg. radiographic devices, digital image/video capture devices, generic devices such as scanners) - Acquiring an image from TWAIN device - Browsing Patient images by date and/or source	Browsing images by date and/or source Viewing an Image Uploading an Image file Acquiring an Image from a Web cam Acquiring an Image from a TWAIN device Acquiring an image from standard dental imaging devices	Similar

Sl. No	Features compared	Proposed Device	Predicate Device	Result
18.	Main Functions	- Viewing an Image, Uploading an Image file - Image Manipulations : Zoom in/out, rotate (by increments of 90 degrees), flipping an image horizontally, resizing an image, adjust brightness-contrast-gamma functions of an image, sharpness enhancement tool - Staff audit logging	Copying an Image to the local computer Saving a Modified Image Annotating an Image, Zooming in on an Image, Inverting Colors on an Image, Rotating an image (increments of 90 degrees), Flipping an image Horizontally or Vertically, Increase and decrease contrast, Increase and decrease brightness, Adjust gamma function, Spotlight sharpness enhancement tool Staff audit logging Staff software-use analytics	
19.	Specifics of Hardware Platform used	System requirements Processor: Intel Core i5 8th generation or greater Memory: 16 GB or more OS: Windows 11, macOS 15 Sequoia or Higher Web Browser: Google Chrome (latest version) Display Resolution: 1366 x 768 Internet Bandwidth: 10 Mbps Up / 10 Mbps Down	Standard PC Hardware OS: Microsoft Windows	Similar
20.	Specifics of Software Platform used	- Hosting environment: AWS EKS -Programming Language: Frontend: Angular, typescript, javascript & Backend: C#, Database:MySQL - Storage: Processed image are stored in AWS S3 storage. - Transfer: Data transfers are done over https.	-Host Platform: Web Based Software Application -On the server side, SOTA Cloud Imaging is written in C# and runs in a stateless containerized environment. -SOTA Cloud Imaging uses Microsoft Azure SQL databases and Microsoft Azure Blob storage to store application metadata and images. -Secure data transmission over (HTTPS, TLS v1.2)	Different
21.	Is OTS (Off-The-Shelf) software used? (either for development or integrated in the device)	Yes	Yes	Same
22.	Web Diagnostic Viewer	Standalone and web-based software suite	Standalone and web-based software	Same

The comparison table evaluates Aeka Imaging against the SOTA Cloud Imaging predicate with respect to intended use, indications for use, environment of use, technical performance, and technological characteristics. This comparison chart offers additional supporting information for the determination of substantial equivalence.

Additionally, the results of the performance testing confirm that Aeka Imaging is safe and effective for its intended use. Based on the intended use, product design, performance data, and software information provided in this submission, Aeka Imaging is considered substantially equivalent to the currently marketed SOTA Cloud Imaging predicate device.

VII. PERFORMANCE DATA

The following non-clinical performance evaluations was conducted as part of Software Verification and Validation for AEKA Imaging.

- Software Unit Test
- Software Integration Test and System Test
- User Acceptance Testing
- Usability Testing
- Cybersecurity Vulnerability and Penetration testing

Bench Performance Testing

The safety and performance of Aeka Imaging were evaluated through bench performance testing conducted as part of design verification and validation activities. Bench performance testing was performed in comparison with the predicate device, SOTA Cloud Imaging (K210682), to verify key functional and performance characteristics, including image quality and orientation, acquisition speed, calibration precision, display latency, image export functionality, and overall system stability.

The evaluations were conducted under representative operating conditions and in accordance with applicable risk management principles and software lifecycle standards. All test results met the predefined acceptance criteria, demonstrating performance equivalent to the predicate device and supporting the safety and effectiveness of Aeka Imaging for its intended use.

The standards applicable

- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION- Medical device software – software life cycle processes
- ANSI AAMI ISO 14971: 2019- Medical devices - Applications of risk management to medical devices
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION- Medical devices - Part 1: Application of usability engineering to medical devices
- NEMA PS 3.1 - 3.20 2024e- Digital Imaging and Communications in Medicine (DICOM) Set

- ISO/IEC 27001:2022Information security, cybersecurity and privacy protection — Information security management systems — Requirements
- IEEE Std 11073-40101-2020- Health informatics - Device interoperability Part 40101: Foundational - Cybersecurity - Processes for vulnerability assessment.
- IEEE Std 11073-40102:2020- Health Informatics - Device interoperability. Part 40102: Foundational - Cybersecurity - Capabilities for mitigation.

The non-clinical performance testing demonstrates that the AEKA Imaging software performs in accordance with its intended use, supporting image acquisition, processing, review, and management in dental clinical workflows. The software qualifies for a basic level of documentation as defined by 'Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff' FDA Guidance document. These results confirm that AEKA Imaging does not raise any new safety or effectiveness concerns and is substantially equivalent to the predicate device.

VIII. CONCLUSION

The subject device and the predicate device SOTA Cloud Imaging (K210682) have similar indications for use, technological characteristics, and principles of operation. Based on the technological characteristics and non-clinical performance testing we conclude that Aeka Imaging is as safe and effective as its predicate device and does not raise any new issues related to safety and effectiveness compared to the predicate. Therefore, the subject device Aeka Imaging is substantially equivalent to the predicate device.