March 3, 2026

SOTA Cloud Corp.
℅ Dustin Johnson
Chief Technology Officer
1073 N Batavia St
Ste B
ORANGE, CA 92867

Re: K251793
Trade/Device Name: SOTA Cloud Smart Sensor (1.5)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: May 23, 2025
Received: January 26, 2026

Dear Dustin Johnson:

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 13484 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, 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)*
K251793

Device Name
Sota Cloud Smart Sensor (1.5)

Indications for Use *(Describe)*

The SOTA Cloud Smart Sensor is a digital intraoral X-ray sensor intended for use in dental practices that utilize X-ray equipment for intraoral diagnostic purposes. The device is intended to be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed and archived digitally.

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 - K251793

February 25, 2026

1. Submitters Information

Name: SOTA Cloud Corp.

Address: 1073 N. Batavia St, STE B

Orange, California, 92867

Official Correspondent: Dustin Johnson

Telephone: (714) 532-6100

E-mail Address: dustin@sotacloud.com

2. Identification of New Device

Submitter: SOTA Cloud Corp.

Owner/Operator: SOTA Cloud Corp.

Establishment Registration Number: 3034604691

Trade Name: SOTA Cloud Smart Sensor(1.5)

Common Name: Digital Intraoral X-ray Sensor

Classification Name: Extraoral Source X-ray System

Regulation Number: 21 CFR 872.1800

Product Code: MUH

Device Class: Class II

3. Identification of Predicate Device

Owner/Operator/Manufacturer: Shenzhen Xpectvision Technology Co., Ltd.

Establishment Registration Number: 3022107311

Trade Names: Digital Intraoral X-Ray Sensor

Models: XVD2121 Plus and XVD2530

Common Name: Dental Intraoral X-ray Sensor

510(k) Number: K220277

Regulation Number: 21 CFR 872.1800

Product Code: MUH

Device Class: Class II

4. Device Description

The SOTA Cloud Smart Sensor is a USB-powered, solid-state digital intraoral X-ray detector intended for use in dental practices. The device is a static detector. X-rays are generated by an external dental X-ray generator. The x-ray generator, an essential component of a fully functional dental imaging system, is not part of the submission.

The device utilizes an indirect detection architecture consisting of:

- Cesium Iodide (CsI) scintillator
- Fiber optic plate
- CMOS imaging device

Incident X-ray photons are converted to visible light by the scintillator and transmitted through the fiber optic plate to the CMOS detector. Image data are transmitted to a host computer through a direct USB connection.

The sensor is portable and is positioned intraorally using standard dental positioning techniques. During clinical use, the sensor is covered with a single-use protective barrier sheath. The sheath is a separate device.

Physical Characteristics

- External dimensions: approximately 29.6 mm × 41 mm
- Effective imaging area: approximately 24.0 mm × 32.8 mm
- Pixel pitch: 18.5 μm
- Resolution: 1296 × 1772 pixels
- Maximum theoretical spatial resolution: 27 lp/mm
- Measured spatial resolution (line pair phantom): 14.3 lp/mm
- Modulation Transfer Function (MTF): 12 lp/mm at 10%, 17 lp/mm at 5%

The device is provided in a Size 1.5 configuration suitable for adult patients and pediatric patients whose oral anatomy accommodates the sensor dimensions.

The device does not perform image interpretation, diagnostic analysis, or automated image enhancement. It outputs raw digital image data to compatible dental imaging software. The dental imaging software is not a part of the subject device.

5. Indications for Use

The SOTA Cloud Smart Sensor is a digital intraoral X-ray sensor intended for use in dental practices that utilize X-ray equipment for intraoral diagnostic purposes. The device is intended to be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed and archived digitally.

6. Comparison of Technological Characteristics

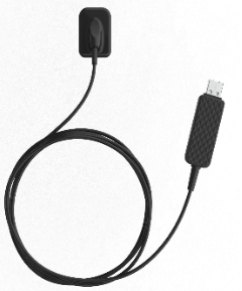
The subject and predicate devices are solid-state digital intraoral X-ray sensors intended for the same clinical application.

Both devices:

- Are intended for intraoral radiographic imaging in dental practice
- Are operated by trained dental professionals
- Are portable sensors placed intraorally using standard positioning techniques
- Connect to a host computer via USB
- Convert X-ray exposure into digital images for display and archiving

Key technological characteristics are summarized below:

Description	Subject Device	Predicate Device
Device/Trade name	SOTA Cloud Smart Sensor	Digital Intraoral X-ray Sensor
510(K) number	K251793	K220277
Classification name	Extraoral Source X-ray System	Extraoral Source X-ray System
Product code	MUH	MUH
Regulation number	21 CFR 872.1800	21 CFR 872.1800
Panel	Radiology/Dental	Radiology/Dental
Classification	II	II
Indications for use	The SOTA Cloud Smart Sensor is a digital intraoral X-ray sensor intended for use in dental practices that utilize X-ray equipment for intraoral diagnostic purposes. The device is intended to be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed and archived digitally.	The digital intraoral X-ray sensors XVD2121 Plus, XVD2530 are intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. Each can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed and archived digitally.
Intended user group	Trained dental professionals	Trained dental professionals

Device components	SOTA Cloud Smart Sensor 	XVD2121 Plus 
		XVD2530 
Sensor area	29.6mm x 41mm	XVD2121 Plus: 26.5mm x 32mm
		XVD2530 31.5mm x 38.5mm
Effective imaging area	24mm x 32.8mm	XVD2121 Plus: 20.0mm x 19.8mm
		XVD2530: 24.6mm x 29.5mm
Deployment methods where relevant	Covered with a protective sheath then placed inside the mouth.	Covered with a protective sheath then placed inside the mouth.
	The device does not directly contact the human body or organ. Note: When used clinically the sensor shall be covered with a protective plastic barrier	The device does not directly contact the human body or organ. Note: When used clinically the sensor shall be covered with a protective plastic barrier

Contact body site	envelope for infection control purposes and then placed inside the mouth during imaging procedure. The protective cover sheath is disposable and is a separate device, NOT a part of this device.	envelope for infection control purposes and then placed inside the mouth during imaging procedure. The protective cover sheath is disposable and is a separate device, NOT a part of this device.
Patient populations	General population (excluding pregnant women) who are evaluated by the dentist to need intraoral X-ray imaging examination.	General population (excluding pregnant women) who are evaluated by the dentist to need intraoral X-ray imaging examination.
Installation type	Portable	Portable
Sensor structure	CsI Scintillator + CMOS	Semiconductor + CMOS ASIC
Limiting spatial resolution (manufacturer-reported)	14.3 lp/mm	7 lp/mm
MTF	12 lp/mm at 0.1	7 lp/mm* **Predicate summary does not specify MTF threshold*
Resolution in Pixels	1296 x 1772 pixels	344x417 pixels (XVD2530)
Pixel pitch	18.5 µm	70 µm
Low contrast resolution	The imaging can distinguish 1mm - diameter hole on aluminum plates	The imaging can distinguish 1mm - diameter hole on aluminum plates

Image non-uniformity	≤ 2%	≤ 2%

The subject device uses an indirect CsI-on-CMOS architecture, while the predicate devices use a direct semiconductor architecture. Despite differences in pixel pitch and detector design, both devices demonstrate comparable modulation transfer function performance at clinically relevant spatial frequencies.

These differences do not alter the intended use and do not raise new questions of safety or effectiveness.

7. Performance Testing

Non-Clinical Testing

The SOTA Cloud Smart Sensor was evaluated for electrical safety, electromagnetic compatibility, and essential performance in accordance with applicable consensus standards, including IEC 60601-1 and IEC 60601-1-2.

Bench testing demonstrated spatial resolution, image uniformity, and low-contrast performance comparable to the predicate devices.

Clinical Performance Evaluation

A qualitative, task-based clinical image evaluation was conducted using representative intraoral radiographs, including anterior periapical, posterior periapical, and bitewing projections.

Independent licensed dentists evaluated the images for diagnostic adequacy using structured criteria addressing:

- Overall image quality
- Spatial resolution
- Contrast
- Uniformity
- Artifact presence
- Suitability for common dental diagnostic tasks

All evaluated images were determined to be diagnostically acceptable for their intended clinical use. No images were rated unacceptable.

Cybersecurity

The SOTA Cloud Smart Sensor is a USB-only device with no wireless capability, network interfaces, or remote connectivity. All interaction occurs locally through a DLL-based API on the host computer.

Cybersecurity evaluation included:

- API authorization controls
- Runtime integrity validation
- Configuration protection
- Secure logging verification
- Structured exception handling
- Resource cleanup validation
- Secure memory clearing of image buffers
- Driver compatibility checks
- Operation under standard user privileges
- Software component vulnerability review

Testing identified no exploitable vulnerabilities. No unauthorized access paths or privilege escalation mechanisms were identified. No residual image data remained in memory after operation.

Residual cybersecurity risk is considered acceptable for the device architecture and intended use.

8. Conclusion

The SOTA Cloud Smart Sensor has the same intended use as the predicate device, Digital Intraoral X-Ray Sensor (K220277), and is intended for use in dental practices to acquire intraoral radiographic images for diagnostic purposes.

The subject and predicate devices are solid-state digital intraoral X-ray detectors that operate under the same fundamental scientific principles and clinical workflow. Both devices are USB-connected, portable intraoral sensors used by trained dental professionals and produce digital images for display and archiving in compatible imaging software.

Although the subject device utilizes an indirect CsI-on-CMOS detector architecture and incorporates a smaller pixel pitch than the predicate, non-clinical bench testing demonstrates comparable spatial resolution, contrast performance, and image uniformity at clinically relevant spatial frequencies. Clinical evaluation further confirms that the

device produces diagnostically acceptable intraoral radiographs suitable for common dental diagnostic tasks.

The identified technological differences do not alter the intended use, do not affect the fundamental operating principles, and do not raise new questions of safety or effectiveness.

Based on the same intended use, comparable technological characteristics, and equivalent performance data, the SOTA Cloud Smart Sensor is substantially equivalent to the predicate device Digital Intraoral X-Ray Sensor (K220277) in accordance with Section 513(i) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 807.100(b).