August 29, 2025

Dentsply Sirona Inc.
Diane Rutherford
Director Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K250771
Trade/Device Name: Primescan 2
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NTK, NBL
Dated: March 14, 2025
Received: July 31, 2025

Dear Diane Rutherford:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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.*

Submission Number *(if known)*

K250771

Device Name

Primescan 2

Indications for Use *(Describe)*

Primescan 2 can be used as a diagnostic aid by licensed dentists for detection of caries on visible tooth surfaces, proximal caries, and tooth cracks.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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510(k) #: K250771

# 510(k) Summary

Prepared on: 2025-08-29

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Dentsply Sirona Inc. |
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## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Primescan 2 |
| Common Name | Laser fluorescence caries detection device |
| Classification Name | Caries Detector, Laser Light, Transmission |
| Regulation Number | 872.1745 |
| Product Code(s) | NTK, NBL |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K182712 | DEXIS CariVu 3-in-1 | NTK, NBL |

## Device Description Summary

21 CFR 807.92(a)(4)

The Primescan 2 is an intraoral scanner that records and generates digital images to provide caries diagnosis support using additional light sources at 405 nm and 850 nm and an optical filter to filter out the excitation light. By illuminating the tooth with these two wavelengths, two diagnosis support modes are realized, the fluorescence mode and the near-infrared mode. The acquired 2D data from the scanner can be viewed in the software in a live stream video during acquisition. The images are also stored in the cloud platform software for later patient communication.

In fluorescence mode, the tooth (or teeth) are illuminated with UV light (405 nm). This stimulates an autofluorescence of the enamel in the green wavelength range. In addition, the red fluorescence is stimulated in carious areas on the teeth. All stimulated fluorescence responses are significantly weaker in terms of their light intensity compared to the back-reflected excitation light. For this reason, the excitation light is filtered out with the aid of an optical filter. The dental professional can use the 2D image data of the fluorescence

response (live stream video) as additional information for caries diagnosis.

For near-infrared mode (NIR mode), the tooth or teeth are illuminated with 850 nm. Enamel is partially transparent in this wavelength. The illumination can therefore penetrate the tooth and is reflected by structural defects such as cracks and cavities, as well as from the dentin core. The reflected light is picked up by the 2D sensor of the scanner.

When used, a sleeve is placed over the distal end of the scanner. This sleeve is the only patient contacting component and is offered as either a single-use disposable or a multi-use sleeve that is reprocessed.

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Primescan 2 can be used as a diagnostic aid by licensed dentists for detection of caries on visible tooth surfaces, proximal caries, and tooth cracks.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The proposed Primescan 2 is intended for the same indications for use as the predicate device DEXIS CariVu 3-in-1 by KaVo (K182712) as a diagnostic aid for detection of dental caries and tooth cracks.

## Technological Comparison 21 CFR 807.92(a)(6)

The proposed Primescan 2 functions in a manner similar to and is intended for the same indications for use as the predicate device DEXIS CariVu 3-in-1 by KaVo (K182712). Both the proposed and predicate devices share the technological characteristics of fluorescence mode, transillumination mode, and CMOS high sensor performance. Both share the principles of operation for fluorescence mode (405nm wavelength) for transillumination mode (850nm wavelength) for visualization of caries.

Some technological differences exist in resolution, focal length, and the patient contacting components. The patient contacting component of the Primescan 2 includes a disposable, single-use sleeve as well as a mutli-use sleeve (requires reprocessing). The predicate uses a disposable sheath with a reusable tip (requiring sterilization). Another difference is the environment in which the software resides. Primescan 2 is a wireless device, operating with a battery and Wi-Fi connection, with software being cloud-native. The ability of the Primescan 2 to function in a completely wireless mode, the size, and power differs from that of the predicate. The software being located in the cloud does not impact the way the scanner performs or functions.

These differences do not raise new concerns of substantial equivalence. The comparison demonstrates substantial equivalence in terms of indications, technology, and performance, with the differences being demonstrated to not impact substantial equivalence. The performance testing demonstrates that the proposed Primescan 2 performs as well as the predicate device.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing performed in support of this eSTAR submission for the Primescan 2 includes the following:
* Performance Validation Testing of the Caries diagnostic Aid - In vivo bench tests demonstrated that Primescan-2 is effective as a diagnostic aid for occlusal caries using the fluorescence function and tooth cracks using the NIR function.
* Photobiological Safety of the LEDs was assessed by an external laboratory in accordance with EN 62471 under worst-case conditions to confirm the safety of the lighting used in the Primescan 2.
* Spatial Resolution Comparison to Predicate Device - Spatial resolution comparison testing was performed where Primescan 2 was compared to the predicate device DIAGNOcam.
* Equivalence testing of Near InfraRed (NIR) and Fluorescence imaging modes for Multiuse sleeve and Single use sleeve - The Multiuse Sleeve and Single use sleeve were tested to be equivalent with respect to using of the near infrared (NIR) and fluorescence imaging modes of the Primescan 2.
* Endurance Testing for Multiuse Sleeve - To demonstrate the reusability of the Multiuse the impact of attaching and detaching sleeves as well as the impact of repeated cleaning, and disinfection were tested.
Additionally, the following guidance and standards were used in the non-clinical testing:
- Electrical Safety & EMC: FDA Guidance: "Electromagnetic Compatibility (EMC) of Medical Devices", IEC 60601-1 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, IEC 60601-1-2 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – requirements and tests, IEC 60601-1-6 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- Wireless Technology: FDA Guidance: "Radio Frequency Wireless Technology in Medical Devices – Guidance for Industry and FDA Staff", IEEE ANSI USEMCSC C63.27– American National Standard for Evaluation of Wireless Coexistence
- Reprocessing: FDA Guidance: "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", ISO 17664-1 – Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices, Part 1: Critical and semi-critical medical devices, AAMI TIR12 – Designing, testing, and labeling medical devices intended for

processing by health care facilities: A guide for device manufacturers, AAMI ST98 – Cleaning validation of health care products – Requirements for development and validation of cleaning processes for medical devices
- Biocompatibility: FDA Guidance: "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'", ISO 10993-1 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, ISO 10993-10 – Biological evaluation of medical devices – Part 10: Tests for skin sensitization, ISO 10993-5 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity, ISO 10993-23 – Biological evaluation of medical devise – Part 23: Tests for irritation
- Software and Cybersecurity: FDA Guidance: "Content of Premarket Submissions for Device Software Functions", IEC 62304 – Medical device software – Software life cycle processes, FDA Guidance: "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"
The conclusions demonstrate that the device is substantially equivalent.