December 14, 2023

SOPRO
Kim Rouahi
Regulatory Affairs & Quality Director
Zac Athelia IV Avenue Des Genevriers
La Ciotat, Bouches-Du-Rhone 13705
FRANCE

Re: K223470
Trade/Device Name: C50
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NBL
Dated: December 1, 2023
Received: December 1, 2023

Dear Kim Rouahi:

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.

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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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)*
K223470

Device Name
C50

Indications for Use *(Describe)*
C50 is intended for clinical practice of general dentistry, as an aid in the diagnosis of pit and fissure caries, as an aid to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) and as intra-oral camera to visualize anatomical details invisible to the naked eye or with a mirror (thanks to magnification).

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.

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510(K) Summary - K223470

Date: December 11, 2023

Submitter:	Name:	SOPRO
	Address:	ZAC Athélia IV – Avenue des Genévriers 13705 LA CIOTAT Cedex
	Contact Person:	Kim ROUAHI +33667690060
Product:	Name of Device:	C50
	Common Name:	Intraoral Camera
	Regulatory Class:	II
	Classification:	21 CFR 872.1745 - Laser, Fluorescence Caries Detection
	Product Codes:	NBL

Predicate Device: K121685 SOPROCARE

Device Description:

The C50 is an intraoral video camera equipped with LEDs to illuminate the inspection site.
The C50 optics and its complementary metal oxide semiconductor (CMOS) sensor capture the natural fluorescence of the site under observation and convert the images into a video signal that is sent to the computer via a USB interface. The dental practitioner can use the images displayed on the computer screen as an aid in diagnosis.

A USB Type-C (camera) to USB-A cable is provided to connect the C50 to a computer.

The C50 provides the following functions:

- Aid in the detection of pit and fissure caries
- Information about patient dental hygiene
- Highlighting of dental plaque
- Highlighting of gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing)
- Showing the difference between “before” and “after” care (follow-up).

In CARIO mode (blue mode), the camera assists the dental practitioner by highlighting potential carious areas in pits and fissures on the occlusal surface of the teeth.

In DAYLIGHT mode (white mode), the camera enables visualization of anatomical details invisible to the naked eye or with a mirror (thanks to its magnification).

DAYLIGHT+ mode (white mode) is a shortcut version of DAYLIGHT mode where the contrast has been pushed from 20 to 70.

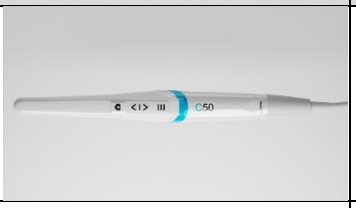
In PERIO mode (yellow mode), the camera helps the dental practitioner to visualize dental plaque, in addition to highlighting areas of gingival inflammation (restricted to gingival inflammation that leads to bleeding upon probing).

Indications for Use:

C50 is intended for clinical practice of general dentistry, as an aid in the diagnosis of pit and fissure caries, as an aid to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) and as intra-oral camera to visualize anatomical details invisible to the naked eye or with a mirror (thanks to magnification).

Technological Characteristics:

Subject and predicate devices are both manufactured by SOPRO. Predicate and subject device technological and performance characteristics are fundamentally the same, as shown by the following table. The subject device includes a device modification to add an additional mode, DAYLIGHT+ mode.

	Predicate Device	*Modified Device/ Subject Device*	*Discussion*
Manufacturer	SOPRO	SOPRO	-
Product Name	SOPROCARE	C50	-
Common Name	Intraoral camera	Intraoral camera	-
Classification Regulation	21 CFR 872.1745 21 CFR 872.1740	21 CFR 872.1745	-
510(k) Number	K121685	K223470	-
Indications for Use	SOPROCARE is intended for clinical practice of general dentistry, as an aid in the diagnosis of pit and fissure caries, as an aid to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) and as intra-oral camera to visualize anatomical details invisible to the naked eye or with a mirror (thanks to its magnification).	C50 is intended for clinical practice of general dentistry, as an aid in the diagnosis of pit and fissure caries, as an aid to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) and as intra-oral camera to visualize anatomical details invisible to the naked eye or with a mirror (thanks to its magnification).	Same
DEVICE DESIGN AND USE			
Design			--
Operational Modes	• CARIO • DAYLIGHT • PERIO	• CARIO • DAYLIGHT • PERIO • DAYLIGHT+	The new DAYLIGHT+ mode is similar to DAYLIGHT mode. It offers a higher-contrast image. The remaining modes are identical.
Focus	4 pre-set positions	Automatic focus or Single focus	The modified device includes automatic focus. The focus range is similar for both devices.
Technology	Fluorescence technology	Fluorescence technology	Same
System of Image Capture	Image capture button on handpiece	Image capture button on handpiece	Same
Accessories	• Intraoral tip • Dedicated protective sheath • Handpiece holder • USB cable	• Intraoral tip • Protective sheath (third party) • Handpiece holder • USB cable	The C50 intraoral camera is intended for use with legally marketed protective sheaths cleared by FDA as a barrier sleeve for intraoral cameras.
User interface	2 button keyboard for mode selection	5 button keyboard for mode selection and on-screen display control	Similar
Power Supply	Docking station	USB	Different
ILLUMINATION AND			

IMAGING			
	Predicate Device	*Modified Device*	*Discussion*
Light Source	LED	LED	Same
Returned Light	Standard image and fluorescence	Standard image and fluorescence	Same
Lens	Multiple lens system with optical glass	Multiple lens system with optical glass	Same
Sensor Resolution	NTSC	Full HD 1920 x 1080	Different
PHYSICAL CHARACTERISTICS			
Dimensions	L = 200mm x W = 28mm x H = 24mm	L = 200mm x W = 30mm x H = 24mm	Similar
Weight	100g	78 g	Similar
Cable Length	3 m	2.5m	Similar
Working temperature	+10 °C / +40 °C	+10 °C / +35 °C	Similar
Working relative humidity	10% to 90%	10% to 90%	Same

Discussion: The modified C50 intraoral camera is very similar to the predicate device SOPROCARE in terms of design, size and weight specifications. Patient contacting materials of the modified and predicate devices are identical in formulation, manufacturing process, processing and geometry.

The On-Screen Display (OSD) of the C50 allows the device to be used with other imaging software (OIS), including Twain or Sopro SDK integration.

The subject device C50 offers Full HD resolution instead of the predicate NTSC resolution, thus enhancing image quality. The C50 is connected to a computer by means of a USB cable.

The C50 intraoral camera is intended for use with legally marketed protective sheaths cleared by FDA as a barrier sleeve for intraoral cameras (product code PEM).

Performance Testing: Design verification and validation testing to support determination of substantial equivalence consisted of the following tests:

- Comparison testing of image quality, sharpness, size, resolution, focus position and potential elevation in the temperature target tissue have been performed using the C50 and the third-party protective sheath and the accessory C50TIPS and have been shown to be substantially equivalent to the predicate device.
- Mechanical performance testing was performed on reprocessed C50TIPS to ensure that the device maintains its position on the C50 camera and completely blocks all external light.
- Mechanical testing was performed with regard to fit of the third-party protective sheath with the C50 and the accessory C50TIPS.
- Electrical safety testing & EMC
  Electrical (IEC 60601-1 and collateral standards) and EMC testing were conducted on the C50 device, consistent with the appropriate sections of the following current standards:
  - IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance and 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/TR 60601-4-2 Medical Electrical Equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- Photobiological safety testing was conducted on the C50 device, consistent with the appropriate section of the following current standard: IEC 62471 Photobiological safety of lamps and lamp systems.
- Software validation was performed on the C50's firmware consistent with the appropriate section of the following current standard: IEC 62304 Software life cycle process.

- Reprocessing validation testing was conducted on the C50, C50TIPS and USB cable in accordance with the recommendations outlined in FDA Guidance Document: "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."
- Biocompatibility testing

  The patient contact materials of C50TIPS were evaluated in accordance with the requirements of international standard ISO 10993-1 (Biological Evaluation of Medical Devices) and FDA Guidance Document "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices -Part 1: Evaluation and Testing within a Risk Management Process". The following biocompatibility tests were considered:

  Chemical
  caracterization
  Cytotoxicity
  Acute Systemic Toxicity

Acceptance criteria were met for all tests performed.

Conclusion: The subject device C50 and its accessories have the same intended use and similar technological characteristics as the predicate device SOPROCARE and the associated accessories. The information provided in this 510(k) submission indicates that the C50 intraoral camera and its accessories (intraoral tip, handpiece holder and USB cable) are substantially equivalent to the predicate device.