September 16, 2022

3Shape TRIOS A/S
Klaus Hoj
Senior Regulatory Affairs Specialist
Holmens Kanal 7
Copenhagen K, Dk-1060
DENMARK

Re: K221249
Trade/Device Name: L1P-1F (TRIOS 5)
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NBL
Dated: August 12, 2022
Received: August 18, 2022

Dear Klaus Hoj:

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/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 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 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, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221249

Device Name
TRIOS 5 (L1P-1F)

Indications for Use *(Describe)*
The L1P-1F intraoral scanner (IOS) system is intended for aid in diagnosis of caries.

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) PREMARKET NOTIFICATION 3SHAPE L1P-1F SYSTEM

510(K) SUMMARY - K221249

Date Summary Prepared

15 September 2022

Submitter's Identification

3Shape TRIOS A/S
Holmens Kanal 7
DK-1060 Copenhagen K
Denmark
Phone: +45 7027 2620
E-mail: info@3Shape.com
Web: www.3Shape.com

Contact:
Klaus Rudbæk Høj
Senior Regulatory Affairs Specialist
Direct phone: +45 3148 8032
E-mail: Klaus_r@3Shape.com

US Agent:
F. David Rothkopf
MEDIcept Inc.
200 Homer Ave
Ashland, MA 01721
Phone: 617-899-3449
E-mail: Drothkopf@MEDIcept.com

Device Identification

Trade / Proprietary Name:	TRIOS 5
Models:	L1P-1F
Common Name:	Intraoral optical scanning system including aid in diagnosis of caries, pod with wireless scanner
Regulation number:	21 CFR 872.1745
Regulation Name:	Laser fluorescence caries detection device.
Product Code:	NBL
Classification:	Class II
Panel:	Dental (76)

Predicate Device

DÜRR DENTAL AG – VistaCam iX "Proof" – K150672

Device Description

The L1P-1F intraoral scanner (IOS) system is intended for aid in diagnosis of caries.The L1P-1F system consists of a scanner and a detachable scanner tip which enables scanning using white and blue (fluorescence) Light Emitting Diodes (LEDs). A single-use scanner body sleeve is mounted on the scanner before being introduced into the mouth of a patient for scanning of the teeth.

The interface to the computer is handled by ScanSuite TRIOS which functions as a Hardware Abstraction Layer (HAL). The scan control of, and information from the scanner is handled by the TRIOS module software, which holds the interface to the user.

The L1P-1F system also consists of the TRIOS Patient Monitoring software which aids in diagnosis of occlusal and surface caries.

The functional principle of L1P-1F (TRIOS 5) is to collect images of the object scanned by means of focus scanning, where light from the LEDs travels through the optical system to the object being scanned and back to an image sensor. 3D true colored images of the teeth combined with 2D green and red image as an additional texture are generated by emitting blue and white light in turn.

Indications for Use

The L1P-1F intraoral scanner (IOS) system is intended for aid in diagnosis of caries.

Summary of the technological characteristics of the new device compared to predicate device

The L1P-1F system is substantially equivalent in terms of indications for use and technology to the VistaCam iX "Proof" manufactured by Dürr Dental AG, which currently is in commercial distribution and FDA cleared under 510(k) #K150672.

Table 1 below, summarizes the technological characteristics of the L1P-1F system vs. the predicate device.

Table 1 Comparison to the predicate device

Comparison criteria	New Device L1P-1F (TRIOS 5) #K221249	Predicate Device VistaCam iX "Proof" 510(k) #K150672
Owner / Operator	3Shape TRIOS A/S	Dürr Dental AG
Manufacturer	3Shape TRIOS A/S	Dürr Dental AG
Comparison		
Intended Use	The L1P-1F intraoral scanner (IOS) system is intended to aid in the detection of tooth decay by measuring increased laser induced fluorescence.	Caries detection aid
Indications for Use	The L1P-1F intraoral scanner (IOS) system is intended for aid in diagnosis of caries.	The VistaCam iX "Proof" is intended to be used as an aid in the detection and diagnosis of dental caries.
Intended Users	The L1P-1F System is to be operated by legally qualified health care professionals in dental clinics.	Dentists and dental personnel.
Main parts	Scanner Detachable scanner tip Communication software between external operating system and scanner	Handpiece Interchangeable head (Proof) Handpiece holder USB connection cable Communication software between PC and handpiece
Accessories and Components	Scanner holder (pod) Wireless dongle Protection tip Batteries and charger Software Body Sleeve	Spacers Hygienic protective cover
Variants	Different packaging configurations	There are different packaging configurations including different heads.
Technology	Technology to obtain 3D digital images based on white light illumination and fluorescence technology to aid in diagnosis of caries.	Fluorescence technology to aid in the detection of carious lesions.
Mode of Operation	The blue-violet light causes tooth structures and bacterial metabolites to fluoresce.	The blue-violet light causes tooth structures and bacterial metabolites to fluoresce
Light Source	1 White LED (broad emission spectrum in the visible) + 2 Blue	4 LEDs at 405 nm (blue-violet light)

Comparison criteria	New Device L1P-1F (TRIOS 5)	Predicate Device VistaCam iX "Proof" 510(k) #K150672
	LEDs at 405 nm (blue-violet light)	
Detection Wavelength	Green to red visible light, > 435 nm	Green to red visible light, 495 nm peak wavelength
Power Supply	Power from batteries	Uses power from PC USB port
Connectivity	Wireless	Wired
Software	TRIOS Module (imaging software) ScanSuite TRIOS (advanced driver software) TRIOS Patient Monitoring (caries detection aid software)	VistaCam iX "Proof" driver software and DSBWIN. VistaCam iX "Proof" can only be used with DBSWIN imaging software
Image Evaluation	3D image color indicating caries stage Red: Moderate/Extensive Yellow: Initial White: Insufficient scan The colors of the diagnostic overlay are derived from the fluorescence texture recorded from the tooth substance	Image Color Relative level Green: 0 - 1.0 Blue: 1.0 - 1.5 Red 1.5 - 2.0 Orange 2.0 - 2.5 Yellow 2.5 - 3.0 Lighter colors and higher numbers indicate an increasing magnitude of the red / green fluorescence ratio and the likelihood of poorer tooth health.
Spatial Resolution	Obtained from many 2D images at different focus positions stitched together	N/A. No publicly available information on spatial resolution performance.
Returned Light	Reflection for white LED illumination Fluorescence for blue LED illumination	Fluorescence
Operating Environment	Ambient temperature range: 15-26°C Relative humidity: 10-85% (non-condensing) Atmospheric pressure: 800-1100 hPa The scanner should be used in an environment maintaining a consistent room temperature	Ambient conditions during operation: Temperature range: 10-40°C Relative humidity: 20-75% (non-condensing) Air pressure: 800-1060 hPa
Materials	**Scanner**: Shell: Polycarbonate Battery inlet: PC/ABS **Scanner tip:**	Handpiece housing: ASA + PC (Acrylonitrile Styrene Acrylate + Polycarbonate) Handpiece control buttons:

Comparison criteria	New Device L1P-1F (TRIOS 5)	Predicate Device VistaCam iX "Proof" 510(k) #K150672
	PSU **Scanner tip window:** Sapphire with FDTS and Al2O3 **Protection tip:** PSU	Polyester Umbilical – Silicone Camera cover: Ethylene methyl Lens window: Glass
Components impacting reprocessing	Scanner tip Body Sleeve	Camera cover Spacer
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-12 ISO 10993-17 ISO 10993-18 ISO 10993-23	ISO 10993-5 ISO 10993-10
Method of sterilization	Autoclave (scanner tip)	Autoclave (only spacer)
Electrical Safety & EMC	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC 80601-2-60

Discussion of Differences

Power Source / Connectivity

The VistaCam iX "Proof" only comes in a wired version whereas the L1P-1F is made in a wireless variant where the power source is batteries.

The batteries are certified and tested according to IEC 62133-2:2017 ('*Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*').

The wireless part complies with 47 CFR, Part 15, and has been tested to comply with IEC 60601-1-2:2014 *('Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances. Requirements and tests')*.

Light Source

The L1P-1F includes two types of LEDs as the light source: one white LED (for 3D image generation) and two blue LEDs (405 nm) as contrary to the predicate device which has four LEDs with blue-violet light (405 nm). The arrangement with two blue LEDs yields sufficient performance for fluorescence detection.

The LEDs have been tested and assessed to be in Risk Group 1 (Low-Risk) according to IEC 62471:2008 ('*Photobiological safety of lamps and lamp systems*').

Detection wavelength

The L1P-1F and predicate device are detecting similar wavelengths and the images are equivalent.

Detection wavelength is >435 nm for L1P-1F and 495 nm for the predicate device. Both devices detect green to red visible light (in particular, L1P-1P for wavelengths above 435 nm).

It is assumed that the predicate device detection wavelength of 495 nm refers to the wavelength of highest sensitivity.

Software

The software package for the L1P-1F consists of the following parts: TRIOS Module (imaging software), ScanSuite TRIOS (advanced driver software), and TRIOS Patient Monitoring (caries detection aid software).

The software package for the VistaCam iX "Proof" consists of the VistaCam iX "Proof" driver software and DSBWIN. VistaCam iX "Proof" can only be used with DBSWIN imaging software.

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*".

The software has been validated according to EN 62304:2006+A1:2015, Medical Device Software Life-Cycle Processes.

Image Evaluation

The color categories used by the two devices to aid image interpretation are named differently.

The predicate device presents four caries severity categories, while the L1P-1F presents two severity caries categories. Table 2 shows how they correspond to each other.

Table 2 Color categories

VistaCam iX Proof	L1P-1F
Early-stage caries, incipient enamel caries	Initial
Enamel caries up to enamel/dentine junction	
Dentin junction already exceeded	
Deep dentin caries	Moderate/Extensive

L1P-1F is following the merged codes of the International Caries Detection and Assessment System (ICDAS) summarizing the first three categories of the VistaCam stages into one.

With the intended use to aid caries diagnosis, the important clinical performance characteristic is to distinguish between a healthy tooth surface and a surface with initial decay or early-stage lesion. The additional caries severity categories that are provided in the predicate device are not expected to trigger any difference in the equivalent clinical performance and safety of caries assessments. However, these early caries stages would usually receive the same non-operative treatment approach by the dental practitioners and the distinction between them would therefore be of less clinical significance as well as reliability.

Spatial Resolution

The spatial (3D) model is obtained from many 2D images at different focus positions stitched together by the imaging software.

There is no publicly available data on spatial resolution for the predicate device. But a qualitative comparison of obtained shows that the resolution of L1P-1F must be at least as good or better than the predicate device.

Components impacting reprocessing

Both L1P-1F and the predicate device have exchangeable tips for scanning and single-use covers.

The predicate device has a protective cover which covers the entire scanner and thus acts as a microbial barrier. The microbial barrier for L1P-1F consists of a protective cover (Body Sleeve) and an autoclavable tip. The Body Sleeve is designed to cover the body of the scanner as well as the base of the detachable tip, which is closed with a window in the front end.

The Body Sleeve has been evaluated to ensure that requirements for clearance of dental barriers and sleeves regulated under 21 C.F.R §878.4370, FDA product code PEM, are met. This included evaluation of tear resistance, tensile strength, puncture resistance, viral penetration, and synthetic blood penetration.

The microbial barrier functionality of the scanner tip has been tested to show that no viral ingress through the tip window will reach the scanner body as tested using the test organism described in ASTM F1671/F1671M-22.

In conclusion, the microbial barrier properties implemented for the L1P-1F system are equivalent to the predicate device and ensures that cleaning and intermediate-level disinfection can be recommended for the scanner body between patients.

Non-Clinical Data

Key performance attributes tested and compared include:

1. Fluorescence scanning
2. Color Separation
3. In vitro caries detection study
4. Spatial resolution

The results of the performance testing demonstrates that L1P-1F is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

Performance Testing

Electrical Safety / Electromagnetic Compatibility (EMC)

Testing was performed for the L1P-1F and complies with:

- IEC 60601-1:2005/AMD1:2012 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
- IEC 60601-1-2:2014 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and Tests)
- IEC 62366-1:2015+ A1:2020 (Medical Devices - Part 1: Application of Usability Engineering to Medical Devices).

Biocompatibility Testing

Patient contact components were evaluated according to relevant recognized standards in the ISO 10993-series. It was concluded that there are no biocompatibility concerns for any of the materials used to manufacture the L1P-1F.

Sterilization

The L1P-1F is not sold as a sterile device.

The Scanner tip is required to be processed prior to first use and between patients. Testing to support recommended methods for reprocessing was performed in accordance with AAMI TIR12:2010 (*'Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical manufacturers'*) and AAMI TIR30:2011+R2016 *('A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices')*.

Conclusion

The proposed device, the L1P-1F, is substantially equivalent to the predicate device Vistacam iX "Proof".

The differences between the proposed and predicate device do not impact the safety and effectiveness of the proposed device. Performance testing supports that L1P-1F is substantially equivalent to the legally marketed predicate device.