April 4, 2025

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

Re: K242103
Trade/Device Name: TRIOS 5 (L1P-1F)
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NBL
Dated: March 6, 2025
Received: March 7, 2025

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 (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K242103

Please provide the device trade name(s).

TRIOS 5 (L1P-1F)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K242103

510(k) Summary

Prepared on: 2025-04-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	3Shape TRIOS A/S
Applicant Address	Holmens Kanal 7 Copenhagen 1060 Denmark
Applicant Contact Telephone	+4531488032
Applicant Contact	Mr. Klaus Høj
Applicant Contact Email	Klaus_r@3shape.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TRIOS 5 (L1P-1F)
Common Name	Laser fluorescence caries detection device
Classification Name	Laser, Fluorescence Caries Detection
Regulation Number	872.1745
Product Code(s)	NBL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221249	TRIOS 5 (L1P-1F)	NBL

Device Description Summary

21 CFR 807.92(a)(4)

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.

3Shape TRIOS A/S modifies L1P-1F (TRIOS 5) to include a single-use tip, TRIOS Ready Tip (TST-15), as an alternative to the already cleared reusable tip (TST-11).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for the subject device is the same as the predicate device:
The L1P-1F intraoral scanner (IOS) system is intended for aid in diagnosis of caries.

Technological Comparison

21 CFR 807.92(a)(6)

The only difference between the subject and predicate device is the introduction of the TRIOS Ready Tip (TST-15) which is a single use tip that can be used as an alternative to the existing reusable tip (TST-11).

The TRIOS Ready Tip (TST-15) has the same function as the reusable tip (TST-11) included in 510(k) premarket notification K221249 in, together with a scanner body sleeve (Body Sleeve), constituting an adequate barrier to reduce the risk of microbial contamination and thereby ease cleaning and disinfection procedures between patients.

A risk analysis was conducted to assess the impact of modifying L1P-1F (TRIOS 5) to include TRIOS Ready Tip (TST-15) as an alternative to the existing reusable tip (TST-11) and adequate risk control measures to mitigate identified risks have been implemented.

Therefore, any differences in technological characteristics between the subject and the predicate device caused by the introduction of the TRIOS Ready Tip (TST-15), does not raise different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

3Shape TRIOS A/S modifies L1P-1F (TRIOS 5) to include a single-use tip, TRIOS Ready Tip (TST-15), as an alternative to the already cleared reusable tip (TST-11).

A risk analysis according to ISO 14971 was conducted to assess the impact of the modification thereby identifying adequate risk control measures to mitigate the identified risks.

Non-clinical tests were performed to verify and/or validate the identified adequate risk control measures following FDA-recognized standards:
- ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 14644-1: Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
- ISO 14698-1: Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1: General Principles and Methods
- ISO 14698-2: Cleanrooms and associated controlled environments – Biocontamination control – Part 2: Evaluation and interpretation of biocontamination data
- ASTM D3078: Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- ASTM F1671/F1671M: Standard Practice for Leaks Using Bubble Emission Techniques
- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 62366-1: Medical devices. Application of usability engineering to medical devices
- IEC 62471: Photobiological safety of lamps and lamp systems

It was concluded that, in terms of safety and effectiveness, the subject device is substantial equivalent to the predicate device.