April 10, 2026

3Shape TRIOS A/S
Jenny Axel
Senior Regulatory Affairs Specialist
Holmens Kanal 7, Copenhagen, 1060 DNK

Re: K260082
Trade/Device Name: TRIOS Dx (R1)
Regulation Number: 21 CFR 872.1770
Regulation Name: Dental Image Analyzer
Regulatory Class: Class II
Product Code: SHQ
Dated: January 12, 2026
Received: January 12, 2026

Dear Jenny Axel:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

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
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.	K260082 ?

Please provide the device trade name(s). ?

TRIOS Dx (R1)

Please provide your Indications for Use below. ?

TRIOS Dx is intended as an aid in the diagnosis of oral health conditions and the assessment of changes in teeth and gingiva.

TRIOS Dx is intended to aid in the diagnosis and assessment of:
- caries
- tooth wear
- gingival recession
- plaque

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

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

510(k) #: K260082

510(k) Summary

Prepared on: 2026-01-12

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	+4550298535
Applicant Contact	Ms. Jenny Axel
Applicant Contact Email	Jenny.Bathke@3Shape.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TRIOS Dx (R1)
Common Name	Dental image analyzer
Classification Name	Dental Image Analyzer
Regulation Number	872.1770
Product Code(s)	SHQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
DEN230035	Dental Monitoring	SBC

Device Description Summary

21 CFR 807.92(a)(4)

Device description summary

TRIOS Dx is a software-only medical device intended to aid dental professionals in the diagnosis of oral health conditions and assessing changes in teeth and gingiva. The device analyzes intraoral scan data using AI/ML-enabled algorithms and displays diagnostic aid results in the user interface for visualization and comparison of scans. Qualified dental professionals review these results alongside a traditional dental examination and communicate findings to the patient.

The software is intended to operate on a generic computing platform running Microsoft Windows and is intended for use in dental clinics by qualified dental professionals. TRIOS Dx is a diagnostic aid device, and it is not intended to replace clinical decision-making. The device has no direct patient contact.

TRIOS Dx accepts intraoral scans from 3Shape scanners or third-party scanners (with limited functionality) and integrates with the 3Shape Unite platform for case management. The user interacts with the device through a graphical interface using a computer mouse, keyboard, or touchscreen. Inputs include 3D dental scans; outputs include diagnostic aid assessments, comparative visualizations, and measurement tools for distances and surfaces.

The device provides features for patient communication, enabling dental professionals to present findings in a clear and understandable format. TRIOS Dx does not require accessories and is marketed in 'Standard' and 'Plus' configurations, based on the active user's license.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

TRIOS Dx is intended as an aid in the diagnosis of oral health conditions and the assessment of changes in teeth and gingiva.

TRIOS Dx is intended to aid in the diagnosis and assessment of:
• caries
• tooth wear
• gingival recession
• plaque

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both the subject and predicate devices are intended to aid in the diagnosis of oral health conditions and to assess changes in teeth and gingiva. Both the subject and predicate devices are intended to aid in the diagnosis of tooth wear, gingival recession, and plaque. Additionally, TRIOS Dx is intended to aid in the diagnosis of caries. The subject device's additional indication for use is claimed based on performance data. This additional indication falls within the same intended use as the predicate device and does not alter the intended therapeutic use of the device. While the indications for use for the subject device are not identical to the predicate device, the differences do not affect the safety and effectiveness of the device relative to the predicate.
In conclusion, all indications for use of the subject device fall within the intended use of the predicate device and, therefore, the two devices have the same intended use.

Three differences between the subject and predicate devices have been identified regarding intended users, intended patient profile, and intended use environment, which do not raise different questions of safety and effectiveness:

• Intended users: The subject device is intended to be operated by qualified dental professionals. The predicate device is intended to be operated by a patient, a non-healthcare professional, or a healthcare professional. The subject device's intended users are a subset of the predicate device's intended users. Software validation demonstrates that the device conforms to user needs in the specified use conditions.

• Intended patient profile: The subject device is intended for patients above 18 years of age. The predicate device is intended for patients above 6 years of age. The subject device's patient population is a subset of the predicate device's patient population. The subject device passed all clinical validation requirements for the intended patient profile.

• Intended use environment: The subject device is intended for use in dental clinics. The predicate device is intended for use in healthcare facilities or in a non-healthcare environment (patient's home). The subject device's clinical context or setting is a subset of the predicate device clinical context or setting. Software validation demonstrates that the device conforms to user needs in the specified use conditions.

Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate device are technologically equivalent as follows:
• Both devices process digital intraoral scans
• Both are software devices with embedded machine learning and locked neural network algorithms aiding in the diagnosis of oral health conditions
• Both devices display oral health conditions within the user interface with a graphical overlay on the intraoral scan
• Both devices assess changes in teeth and gingiva
• Both workflows include a patient profile set-up, intraoral scan upload, analysis of uploaded intraoral scans, and communication of results
• Both devices' user interfaces include a computer, a display, a keyboard and a mouse or a touch screen
• Both are software devices designed to run on Windows operating systems

Three technological differences between the subject and predicate devices have been identified, which do not raise different questions of safety and effectiveness:

• Operating system: The predicate device is intended to operate on a broader range of platforms and operating systems than the subject device.

• Input specifications: The predicate device employs a broader range of input specifications than the subject device.

• Accessories and hardware components: The predicate device requires accessories and hardware components used to remotely track treatment progress, a feature which is not claimed by the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing included bench evaluations of the TRIOS Dx diagnostic aid functionality for proximal caries. All tests met the predefined acceptance criteria and demonstrated that TRIOS Dx performs as intended under anticipated conditions of use. These results support the additional indication for use (proximal caries) claimed for the subject device.

Clinical testing evaluated the TRIOS Dx performance for the following diagnostic aid indications:
• Plaque: n=60 subjects; single-arm cross-sectional clinical study; study location: United Kingdom
• Gingival Recession: n=109 subjects; single-arm cross-sectional clinical study; study location: United Kingdom
• Tooth Wear: n=61 subjects; single-arm cross-sectional clinical study; study location: United Kingdom
• Surface Caries: n=34 subjects; single-arm cross-sectional clinical study; study location: Denmark

Studies were conducted under Good Clinical Practice (GCP), registered on ISRCTN or clinicaltrials.gov, and adhered to ethical principles of the Declaration of Helsinki.

Clinical testing demonstrated adequate sensitivity and specificity for the diagnostic aid indications plaque, gingival recession, tooth wear, and surface caries. No adverse events or complications were reported.
Both the subject and predicate devices are intended to aid in the diagnosis of plaque, gingival recession, and tooth wear. Additionally, TRIOS Dx is intended to aid in the diagnosis of caries. The subject device's additional indication for use is claimed based on performance data. This additional indication falls within the same intended use as the predicate device and does not alter the intended therapeutic use of the device, nor does it affect the safety and effectiveness of the device relative to the predicate.

These results support the additional indications for use (surface caries) claimed for the subject device, confirm that the subject device performs as intended under anticipated conditions of use in the intended use population, and support substantial equivalence to the predicate device.

Non-clinical and clinical testing relied upon for substantial equivalence demonstrate that TRIOS Dx is as safe and as effective as the predicate device. Bench testing for proximal caries confirmed that the subject device performs as intended under anticipated conditions of use. Clinical testing showed adequate sensitivity and specificity for the plaque, gingival recession, tooth wear, and surface caries diagnostic aid indications without reported adverse events, and confirmed that the subject device performs as intended under anticipated conditions of use in the intended use population. These results support the conclusion that TRIOS Dx is substantially equivalent to the predicate device.