November 17, 2025

Nobel Biocare c/o Medicim NV
℅ Mieke Roelants
RA Manager
Stationsstraat 102
MECHELEN, 2800
BELGIUM

Re: K252086
Trade/Device Name: DTX Studio Assist
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN, QIH
Dated: October 14, 2025
Received: October 14, 2025

Dear Mieke Roelants:

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,

Lu Jiang

Lu Jiang, Ph.D.
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DHT8B: Division of Radiologic Imaging
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Office of Product Evaluation and Quality
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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.

510(k) Number *(if known)*
K252086

Device Name
DTX Studio Assist

Indications for Use *(Describe)*
DTX Studio Assist is a Software Development Kit (SDK) designed to integrate with medical device software that displays two-dimensional dental radiographs. It contains a selection of algorithms that processes input data (two-dimensional radiographs) from the hosting application and returns a corresponding output to it.
DTX Studio Assist is intended to support the measurement of alveolar bone levels associated with each tooth. It is also intended to aid in the detection and segmentation of non-pathological structures (i.e., restorations and dental anatomy).

DTX Studio Assist contains a computer-assisted detection (CADe) function that analyzes bitewing and periapical radiographs of permanent teeth in patients aged 15 and older to identify and localize dental findings, including caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration, and bone loss.

DTX Studio Assist is not intended as a replacement for a complete dentist's review nor their clinical judgment which takes into account other relevant information from the image, patient history, and actual in vivo clinical assessment

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.

510(k) #: K252086

510(k) Summary

Prepared on: 2025-10-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nobel Biocare c/o Medicim NV
Applicant Address	Stationsstraat 102 Mechelen 2800 Belgium
Applicant Contact Telephone	003215 44 32 00
Applicant Contact	Mrs. Mieke Roelants
Applicant Contact Email	DEN-MEC-DTX-Regulatory@envistaco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DTX Studio Assist
Common Name	Medical image analyzer
Classification Name	Medical Image Analyzer
Regulation Number	892.2070
Product Code(s)	MYN, QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231898	DTX Studio Clinic 4.0	MYN
K242437	Smile Dx	MYN

Device Description Summary

21 CFR 807.92(a)(4)

DTX Studio Assist is a software development kit (SDK) that makes a selection of algorithms (including AI-based algorithms) available through a clean, well-documented API. DTX Studio Assist features are only available to licensed customers. The SDK has no user interface and is intended to be bundled with and used through other software products (hosting applications).

Key functionalities of DTX Studio Assist include:

Focus Area Detection on IOR images: The software features the Focus Area Detection algorithm which analyzes intraoral radiographs for potential dental findings (caries, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration, bone loss and calculus) or image artifacts.

Alveolar Bone Level Measurement: The software enables the measurements of mesial and distal alveolar bone levels associated with each tooth.

Detection of historical treatments: The software enables automated detection and segmentation of dental restorations in IOR images to support dental charting which can be used during patient communication. The following restoration types are supported: amalgam

fillings, composite fillings, prosthetic crowns, bridges, implants, implant abutments, root canal fillings and posts.

Anatomy Segmentation: The software segments dental structures by assigning a unique label to each pixel in IOR images, including enamel, dentine, pulp, bone, and artificial structures.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

DTX Studio Assist is a Software Development Kit (SDK) designed to integrate with medical device software that displays two-dimensional dental radiographs. It contains a selection of algorithms that processes input data (two-dimensional radiographs) from the hosting application and returns a corresponding output to it.
DTX Studio Assist is intended to support the measurement of alveolar bone levels associated with each tooth. It is also intended to aid in the detection and segmentation of non-pathological structures (i.e., restorations and dental anatomy).

DTX Studio Assist contains a computer-assisted detection (CADe) function that analyzes bitewing and periapical radiographs of permanent teeth in patients aged 15 and older to identify and localize dental findings, including caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration, and bone loss.

DTX Studio Assist is not intended as a replacement for a complete dentist's review nor their clinical judgment which takes into account other relevant information from the image, patient history, and actual in vivo clinical assessment

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device, DTX Studio Assist and the first predicate device DTX Studio Clinic 4.0 are predominantly equivalent in terms of Indications for Use regarding the CADe functionality (Focus Area Detection):

Both devices are CADe systems that analyze intraoral radiographs to identify and localize dental findings such as caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration, and bone loss. They are intended for use by dental professionals reviewing bitewing and periapical radiographs of permanent teeth in patients aged 15 years or older.

The difference in Indications for Use between the subject and primary predicate device concerns the additional functionalities of DTX Studio Assist, which include:
- Measurement of alveolar bone levels
- Detection and segmentation of restorations
- Segmentation of dental anatomy

These additional functionalities are present in the secondary predicate device, Smile Dx (K242437), which also supports segmentation and measurement capabilities, including bone level assessment and identification of restorations and dental anatomy.

Conclusion

The subject device, DTX Studio Assist, encompasses the combined Indications for Use of both predicate devices. The differences in wording reflect the inclusion of additional functionalities and do not constitute a new intended use. The overall intended use, supporting dental professionals in the review of intraoral radiographs, remains consistent across the subject and predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

DTX Studio Assist and primary predicate device (DTX Studio Clinic 4.0 - K231898) share the following characteristics:
- Supervised machine learning algorithms
- Detection of six dental findings
- Use of intraoral radiographs (bitewing and periapical)
- Output via bounding boxes and segmentation masks
- Intended use by dental professionals

There are no technical differences between the Focus Area detection algorithm in DTX Studio Clinic 4.0 (primary predicate - K231898) and the algorithm in the current subject device.

DTX Studio Assist and the secondary predicate device (Smile Dx - K242437) share the following characteristics:
- Supervised machine learning algorithms

- Detection of caries and periapical radiolucencies
- Segmentation of dental anatomy
- Use of bitewing and periapical radiographs
- Support measurement of mesial and distal alveolar bone levels
- Intended use as an adjunct tool for dental professionals

DTX Studio Assist is technologically different from the predicate devices as follows:

- DTX Studio Assist is technologically different from the primary predicate device in that it includes only a limited subset of functionalities derived from DTX Studio Clinic; key features such as implant planning and other advanced capabilities are not part of DTX Studio Assist.
- DTX Studio Assist is a Software Development Kit (SDK) that outputs structured results for integration into a hosting application, unlike predicate devices such as DTX Studio Clinic and Smile Dx which are stand-alone or web-based applications that display findings directly on radiographs; this architectural difference does not raise safety or effectiveness concerns, as the SDK's output is consistently interpreted and visualized by the host software in a controlled, documented, and validated environment.

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

DTX Studio Assist is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485:2016 Standards. This device is in conformance with the applicable parts of IEC 62304:2006/Amd 1:2015 standard. Design Control Activities, including risk management following the ISO 14971:2019, verification/validation testing, were conducted and are included in this submission.

The performance of the subject device was verified and validated following the guidance provided in FDA Guidance General Principles of Software Validation. This documentation includes testing which demonstrates that the requirements for the features have been met. Software documentation for Basic Documentation Level of Concern description of respective V&V activities, per the FDA guidance document, "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, is also included as part of this submission.

Nonclinical Performance Testing Summary

I. Focus Area Detection (CADe functionality-MYN)
This functionality was originally cleared under K221921. The standalone performance testing results supporting this feature are included in that submission.

II. New software feature performance testing
Three new stand-alone validation studies were conducted to support the determination of substantial equivalence for the newly developed software features: the restoration detection and the Alveolar Bone level measurement algorithm.
1. Restoration Detection Algorithm
A standalone performance assessment was conducted to evaluate the DTX Studio Assist IOR Restoration Detection algorithm independently, without interaction from dental professionals, in identifying and segmenting eight types of dental restorations in intraoral radiographs (IORs). The study included 1,530 IOR images collected from dental practices across the United States and Europe. The dataset was composed of 41% bitewing and 59% periapical images, with 91% captured using digital sensors and 9% using photostimulable phosphor (PSP) plates. The patient population was 38% male and 62% female, with a broad age distribution. Images were sourced from nine U.S. states and multiple European sites to ensure geographic and demographic diversity. The study used a two-out-of-three consensus method to establish a reference standard. The algorithm achieved an overall sensitivity of 88.8% and specificity of 96.6%, with segmentation accuracy confirmed by a mean Dice score of 86.5%, closely matching inter-expert agreement
2. Alveolar Bone Level (ABL) Measurement Algorithm
A standalone performance assessment was conducted to evaluate the DTX Studio Assist IOR Alveolar Bone Level (ABL) Measurement algorithm independently, without interaction from dental professionals, in identifying anatomical landmarks and calculating mesial and distal ABL measurements in intraoral radiographs (IORs). The study included 274 IOR images collected from 30 dental practices across the United States and Europe. The dataset consisted of 45% bitewing and 55% periapical images, with 86% captured using digital sensors and 14% using photostimulable phosphor (PSP) plates. The patient population was 39% male and 60% female, with a broad age distribution. Images were sourced from multiple U.S and European sites to ensure geographic and demographic diversity. A two-out-of-three consensus method was used to establish a reference standard. The algorithm achieved a sensitivity of 93.2% and specificity of 88.6% for ABL line segment matching. In addition, with an average mean average error of 0.26 mm, the ABL length measurements showed an MAE well below the 1.5 mm threshold, confirming the length is correctly measured by the algorithm.
3.Anatomy Segmentation Algorithm
A standalone performance assessment was conducted to evaluate the DTX Studio Assist IOR Anatomy Segmentation algorithm independently, without interaction from dental professionals, in identifying and segmenting key anatomical structures in intraoral radiograph images (Enamel, Dentine, Pulp , Jaw bone, artificial). The study included 220 IOR images collected from dental practices

across the United States and Europe. The dataset was composed of 51% bitewing and 49% periapical images. This study report demonstrated that the IOR Anatomy Segmentation Algorithm performs with high accuracy and reliability across a diverse set of 220 intraoral radiographs. The algorithm demonstrated strong performance, achieving an overall average Dice score of 86.5%, an overall average sensitivity of 89.0%, and an overall average specificity of 95.2%. The results are deemed reliable as attested by their tight confidence intervals. The results demonstrate that the algorithm is well suited for integration into dental workflows as a tool to support dental professionals in patient communication.

Clinical performance data were submitted in support of the Focus Area Detection functionality, which was previously cleared under 510(k) K221921. A retrospective, fully crossed, multi-reader, multi-case (MRMC) study was conducted to evaluate the clinical performance of the IOR Focus Area Detection algorithm.
The study demonstrated that the aid of the algorithm significantly improved dentists' diagnostic detection and localization performance for dental findings in intraoral radiographs (IORs). The primary endpoint was a statistically significant increase in the Area Under the Curve (AUC) in the aided arm compared to the unaided control arm, based on AFROC (Alternative Free Response Receiver Operating Characteristic) analysis.
The dataset included 216 periapical and bitewing IOR images acquired in U.S.-based dental offices using either sensors or photostimulable phosphor plates.
Thirty readers participated in the study. Half began with unaided reading, while the other half used the AI-assisted system. After a 4-week washout period, the groups switched modalities. The analysis showed a highly significant AUC increase ($p < 0.001$) of 8.7% overall in the aided arm.
For detailed results and analysis, please refer to the original 510(k) submission K221921.

Based on the comparison of the intended use, the features and workflows, the technical characteristics, and based on the software verification/validation activities described in this submission, DTX Studio Assist is found to be substantially equivalent to the identified Predicate Devices.