December 8, 2023

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

Re: K231898
Trade/Device Name: DTX Studio Clinic (4.0)
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: November 13, 2023
Received: November 13, 2023

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.

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.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231898

Device Name

DTX Studio Clinic (4.0)

Indications for Use *(Describe)*

DTX Studio Clinic is a software program for the acquisition, management, transfer and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental restorative solutions.
It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations.
It can be used to support guided implant surgery whereby the results can be exported.
DTX Studio Clinic is a computer assisted detection (CADe) device that analyses intraoral radiographs to identify and localize dental findings, which include caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration and bone loss. The DTX Studio Clinic CADe functionality is indicated for use by dentists for the concurrent review of bitewing and periapical radiographs of permanent teeth in patients 15 years of age or older.

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) #: K231898

510(k) Summary

Prepared on: 2023-12-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nobel Biocare AB
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DTX Studio Clinic (4.0)
Common Name	Medical image analyzer
Classification Name	Medical image analyzer
Regulation Number	892.2070
Product Code	MYN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221921	DTX Studio Clinic 3.0 (Focus Area Detection)	MYN
K213562	DTX Studio Clinic 3.0	LLZ
K163122	NobelClinician®, DTX Studio Implant	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

DTX Studio™ Clinic is a software interface for dental/medical practitioners used to analyze 2D and 3D imaging data, in a timely fashion, for the treatment of dental, craniomaxillofacial and related conditions. DTX Studio Clinic displays and processes imaging data from different devices (i.e. Intra/Extra Oral X-Rays, (CB)CT scanners, Intraoral scanners, intraoral and extraoral cameras).

DTX Studio Clinic features an AI-powered Focus Area Detection algorithm which analyzes 2D intraoral radiographs for potential dental findings or image artifacts. The detected focus areas can be converted afterwards to diagnostic findings after approval by the user.

The following dental findings can be detected by the device:
• Caries: Caries is defined as caries, showing as area with radiographically lower density on a tooth, but does not include occlusal secondary caries under dental fillings.
• Discrepancy at margin of an existing restoration: A discrepancy at margin is defined as radiographically visible discontinuities (gaps, spaces, overhangs) between outline/margin of dental restoration (e.g, fillings, inlays or crowns/bridges) and remaining tooth substance, also called as `misfit', `poor fit' or `not-perfectly seated'. Note that non-radiopaque cement/bonding material may radiographically appear as a space.
• Periapical radiolucency: A periapical radiolucency is defined as a radiolucent area or radiographic observation of low bone density related to the apical part of the root. A widening of the periodontal ligament is not included.
• Root canal filling deficiency: The root canal filling appears radiographically too short (more than 2mm from the radiographic apex) and/or too small in diameter, or the root filling is not radiographically homogenously dense (e.g., with visible void in root filling or gaps between filling and root dentin), or otherwise show absence of radio-opaqueness.
• Bone loss: Bone loss is defined as a radiographically lower density of the marginal bone and/or a lower crest of the alveolar bone compared to what is considered normal for healthy natural dentition. Healthy natural dentition refers to teeth that have not experienced any marginal bone loss and have an alveolar bone that covers the root of the tooth. It is indicated by a focus area annotation, however, the size of the rectangular bounding box is not indicative of the amount of bone loss.
• Calculus: Calculus is a hard, mineralized form of dental plaque that is visible on radiographic images as radiopaque material attached to the tooth surface.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

DTX Studio Clinic is a software program for the acquisition, management, transfer and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental restorative solutions.
It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations.
It can be used to support guided implant surgery whereby the results can be exported.
DTX Studio Clinic is a computer assisted detection (CADe) device that analyses intraoral radiographs to identify and localize dental findings, which include caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration and bone loss. The DTX Studio Clinic CADe functionality is indicated for use by dentists for the concurrent review of bitewing and periapical radiographs of permanent teeth in patients 15 years of age or older.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject and the predicate device DTX Studio Clinic 3.0 (Secondary predicate - K213562) are predominantly equivalent in terms of indications for Use.

Both devices allow the import, visualization, and enhancement of medical images from various sources. By doing so, these devices both support the diagnostic and treatment planning process in dental and craniomaxillofacial regions.

Both the subject and secondary predicate device are software solutions indicated for the display and processing of medical image information and are intended to support the diagnostic process predominately within dentistry. Oral and maxillofacial surgeons offer treatments which can cover the complete craniomaxillofacial area (including the dental area). For this reason, both devices allow the user to visualize and evaluate data for the entire craniomaxillofacial area, as a support for the diagnostic process.

In addition, both the subject and the secondary predicate provide design input for restorative solutions to 3rd party software or software from DTX Studio ecosystem, but it does not provide functionality of designing restorations within the software itself.

Lastly, they also allow for retrieving and storage of image data within the system (locally) or across computer systems at different locations. DTX Studio Clinic 4.0, just like the secondary predicate device allows transfer of images and patient data (store and retrieval) to and from the DTX Studio Core database, thus making the data available at different locations.

The difference in Indications for Use between the subject and predicate devices is that the indication for use of the secondary predicate device was extended with the Focus Area Detection functionality of the primary predicate (K221921) and with the Guided Implant planning functionality of the tertiary predicate (K163122).

-The Focus Area Detection functionality is shared with the predicate device (primary predicate K221921) and thus the following was added:
“DTX Studio Clinic is a computer assisted detection (CADe) device that analyses intraoral radiographs to identify and localize dental findings, which include caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing

restoration and bone loss. The DTX Studio Clinic CADe functionality is indicated for use by dentists for the concurrent review of bitewing and periapical radiographs of permanent teeth in patients 15 years of age or older."

-The Guided Implant Planning is shared with the predicate device NobelClinician (third predicate K163122); hence the following sentence was added:
"It can be used to support guided implant surgery whereby the results can be exported."

Based on the above assessment of the indications for use, we conclude that the subject and the combined predicate devices have similar indications for use statements. Slight differences in wording allow for clarity and align with the added functionality within the subject device.
These changes in the indications for use statement do not constitute a new intended use of the product.

Technological Comparison

21 CFR 807.92(a)(6)

DTX Studio Clinic 4.0 and the primary predicate device (K221921) share the following characteristics:

The entire Focus Area Detection functionality without adjustments was added as functionality to the subject device. This functionality entails:
• Automated Detection
• Output: Message indicating if and how many dental findings are detected
• Set of togglable bounding boxes around suspected dental findings
• Dental Findings: Caries, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration, bone loss and calculus
• Reader workflow: Concurrent Reading
• Algorithm: Supervised machine learning

DTX Studio Clinic 4.0 incorporates all the functionalities from the secondary predicate device (K213562) and shares all functionalities, including:
• Treatment of same anatomic areas
• Type of input data
• Image import and adjustment methods
• Intraoral scanner: Import of surface scan files and their registration with other scans
• The diagnostic module allows to review and diagnose 2D and 3D image data as well as clinical images. The user can apply image filters and can measure length, angles, and HU units. The software allows to compare 3D images and 2D intraoral images in the same workspace
• Visualization of airways, volume segmentation, volume measurement and maximum constriction point determination.
• Automatic annotation of the mandibular canals based on anatomical landmarks
• Automatic sorting algorithm: Intraoral radiograph (IOR) automatic image sorting to an FMX template (dental X-ray image layout)
• Virtual tooth setup: Algorithm calculates and visualizes a 3D tooth shape for a missing tooth position, based on a set of indicated landmarks and the loaded intra-oral scan Enhancement (image filter application), annotations, measurements (distance and angular, volume and surface area for data segmentation), import/export.
• Airway volume segmentation.
• Alignment of surface scans, such as intra-oral or dental cast scans .STL/.PLY files with (CB)CT data for accurate implant planning
• Type of output data
• Operation System and hardware requirements

DTX Studio Clinic 4.0 and the third predicate device (K163122) share the following characteristics:

• Treatment of same anatomic areas
• Support image-based diagnostic process and treatment planning of dental, cranio-maxillofacial, and related treatments.
• Visualization of 2D and 3D images to bring diagnostic image data together.
• Surgical template design from surface data (output is stl file)

DTX Studio Clinic is technologically different from the predicate devices as follows:
DTX Studio Clinic 4.0 incorporates 2 additional functionalities when compared to the secondary predicate (K213562).

• The first functionality concerns the unchanged Focus Area detection, an AI-powered Focus Area Detection algorithm which analyzes intraoral radiographs for potential dental findings or image artifacts, and which was cleared in primary predicate K221921. There are no functional or technical differences between the Focus Area detection in DTX Studio Clinic 3.0 (primary predicate - K221921) and the current subject device.

• The second functionality allows the user of DTX Studio Clinic to create a digital surgical template file (.stl file) from an implant plan. This algorithm was originally implemented in DTX Studio Implant (NobelClinician (third predicate - K163122)) and is now incorporated in the DTX Studio Clinic 4.0 software. The algorithm was unchanged related to the fitting of the template on the dental surface and the creation of sleeve holes within the digital surgical template file. A comparison of the digital surgical template file generated by DTX Studio Clinic 4.0 with the file created in DTX Studio Implant was performed. The test report shows that DTX Studio Clinic 4.0 created - for the same implant plan - a similar surgical template file with the same fitting surface and sleeve hole design as in DTX Studio Implant.

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

DTX Studio Clinic 4.0 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 Moderate Level of Concern and description of respective V&V activities, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, is also included as part of this submission.

Software Validation
Software verification and validation testing was conducted on the subject device 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".

A comparative analysis between the output of the focus area detection algorithm of the subject device and the output of the primary predicate device (K221921) was performed. The test results show that for each intraoral x-ray image, the focus area detection is executed, and the same number of focus areas were detected compared to the predicate device. All detected bounding boxes were identical and the acceptance criteria was met.

The algorithm which allows the DTX Studio Clinic 4.0 user to create a digital surgical template file (.stl file) from an implant plan was originally implemented in DTX Studio Implant (NobelClinician (third predicate - K163122)). The algorithm was unchanged related to the fitting surface of the template on the dentition and the creation of sleeve holes within the digital surgical template file. A comparison of the digital surgical template file generated by DTX Studio Clinic 4.0 with the file created in DTX Studio Implant was performed. The test report shows that the surgical template file created in DTX Studio Clinic 4.0 has the same fitting surface and sleeve hole design as in DTX Studio Implant for the same implant plan parameters.

N/A

Based on the comparison of the intended use, the features and workflows, the user interface, the technical characteristics, and based on the software verification/validation activities described in this submission, DTX Studio Clinic 4.0 is found to be substantially equivalent to the identified Predicate Devices.