March 25, 2022

Nobel Biocare AB
% Wim Vrydag
QA/RA Manager
Nobel Biocare c/o Medicim NV
Stationsstraat 102
Mechelen, 2800
BELGIUM

Re: K213562
Trade/Device Name: DTX Studio Clinic 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 18, 2022
Received: February 22, 2022

Dear Wim Vrydag:

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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K213562

Device Name
DTX Studio Clinic 3.0

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.

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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1. 510(k) Summary

I. Submitter

Submitted by:
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Submitted for:
Nobel Biocare AB
Vastra Hamngatan 1
Göteborg, SE-411 17, Sweden
Establishment Registration No. 9611992
Date Prepared: January 18, 2022

II. Device

Name of Device: DTX Studio Clinic 3.0
Manufacturer: Nobel Biocare AB
Common or Usual Name: Medical Image Management and Processing System
Classification Name: System, Image Processing, Radiological
CFR Number: 892.2050
Regulatory Class: II
Product Code: LLZ

III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary Predicate:
Predicate Device: DTX Studio Clinic
Predicate 510(k): K203156
Company: Nobel Biocare AB
Common or Usual Name: Medical Image Management and Processing System
Classification Name: System, Image Processing, Radiological
CFR Number: 892.2050
Regulatory Class: II
Product Code: LLZ

Reference device:
Reference Device: InvivoDental
Reference 510(k): K123519
Company: Anatomage Inc.
Common or Usual Name: Medical Image Management and Processing System
Classification Name: System, Image Processing, Radiological
CFR Number: 892.2050
Regulatory Class: II
Product Code: LLZ

IV. Device Description

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. intraoral X-Rays, (CB)CT scanners, intraoral scanners, intraoral and extraoral cameras).

V. Indications for Use

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.

VI. Comparison of Technological Characteristics

The subject and predicate device are software-based data visualization tools which allow for transfer of medical images and enhancement with intention to support diagnostic process and treatment planning of craniomaxillofacial patients.

Summary comparison of technological similarities and differences

The subject device DTX Studio Clinic 3.0 and the predicate device DTX Studio Clinic 2.0 share following characteristics:

- Clinical Use – intended to support the diagnostic and treatment planning process of craniomaxillofacial anatomical area
- Clinical image data import and acquisition from supported devices, data visualization, distance and angular measurements

- Image enhancement – image filter application, annotations
- Airway volume segmentation
- Intraoral radiograph (IOR) automatic image sorting to an FMX template
- Dental implant planning
- Patient data management features

DTX Studio Clinic 3.0 is different from the predicate device DTX Studio Clinic 2.0 as follows:

- Automatic annotation of the dental mandibular canal
- Importing Face scan
- Removal Intra oral scanner module (NOF)

A comparison of the subject and predicate devices is provided in the table below.

Table 1: Comparison of DTX Studio Clinic to Predicate Devices

Criteria	DTX Studio Clinic 3.0 (subject device)	DTX Studio Clinic 2.0 (Primary predicate device) K203156	InVivoDental (reference device for automatic annotation of mandibular canal) K123519	Comments
Indications for Use Statement	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.	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.	InVivoDental is a software application used for the display and 3D visualization of medical image files from scanning devices, such as CT, MRI, or 3D Ultrasound. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, store, print, assist in diagnosis, and dis tribute images utilizing standard PC hardware. Additionally, InVivoDental is a preoperative software application used for the simulation and evaluation of dental implants, orthodontic planning and surgical treatments	Same
Classification code	LLZ	LLZ, NOF	LLZ	
Input data/Image acquisition	DICOM image data volumes, 2D and 3D images such as (CB)CT scans and 2D images such as OPG/panorex images, acquisition of X-Ray images from intra-oral sensors, cephalometric images, intra-oral images, clinical pictures and face scans	DICOM image data volumes, 2D and 3D images such as (CB)CT scans and 2D images such as OPG/panorex images, acquisition of X-Ray images from intra-oral sensors, cephalometric images, intra-oral images and clinical pictures.	2D and 3D images such as CT and MRI, optical scans STL or PLY and prosthetic designs of restorations, photos. Image Capture and Export AVI (Movie) Capture and Export Import from PACS	Different – See discussion below

	STL, NXA, PLY files from intraoral and optical scanner.	STL, NXA, PLY files from intraoral and optical scanner.		
Output data	Data is stored locally or in remotely accessible database in the network (DTX Studio Core). 2D and 3D image export (DICOM image data volumes, 2D and 3D images such as (CB)CT scans and 2D images such as OPG/panorex images, acquisition of X-Ray images from intra-oral sensors, cephalometric images, intra-oral images and clinical pictures.), STL, PLY, NXA file export. Export implant or restorative treatment plan Diagnostic findings report export.	Data is stored locally or in remotely accessible database in the network (DTX Studio Core). 2D and 3D image export (DICOM image data volumes, 2D and 3D images such as (CB)CT scans and 2D images such as OPG/panorex images, acquisition of X-Ray images from intra-oral sensors, cephalometric images, intra-oral images and clinical pictures.), STL, PLY, NXA file export. Export implant or restorative treatment plan Diagnostic findings report export.	Data is stored locally. 2D and 3D image export (DICOM image data volumes, 2D and 3D images such as (CB)CT scans and 2D images such as OPG/panorex images, acquisition of X-Ray images from intra-oral sensors, cephalometric images, intra-oral images and clinical pictures.), STL, PLY, NXA file export.) Export data in DICOM/DICOMDIR format or proprietary format, including treatment plans with implants and measurements, traced nerves or other annotations, images captured, sculpting operations, imported models, ortho tracings from 3D analysis. Export optionally with a proprietary viewer or with web browser-based 3D viewer. Export to PACS	Same
Image processing	Enhancement (image filter application), annotations, measurements (distance and angular, volume and surface area for data segmentation), import/export. Airway volume segmentation.	Enhancement (image filter application), annotations, measurements (distance and angular, volume and surface area for data segmentation), import/export. Airway volume segmentation.	Enhancement (image filter application), annotations, Linear, Angular, Circumferential, Area, and Volumetric Measurements (distance and angular, volume and surface area for data segmentation), bone density evaluation, import/export. Creation of fly-through / presentation movies in AVI format.	Same

	Alignment of surface scans, such as intra-oral or dental cast scans .STL/.PLY files with (CB)CT data for accurate implant planning	Alignment of surface scans, such as intra-oral or dental cast scans .STL/.PLY files with (CB)CT data for accurate implant planning	Airway volume segmentation. Endo visualizations. TMJ visualizations. Automatic Superimposition and Mirroring Alignment of surface scans, such as intra-oral or dental cast scans .STL/.PLY files with (CB)CT data for accurate implant planning.	
Software Features	**Scan data:** The software can directly acquire images from supported imaging modalities or allow manual import of images by import dialog. The data can be manually adjusted with the wizard editor. The data can be also imported from 3rd party patient management systems via standard protocol – VDDS, or via Nobel Biocare proprietary OPP protocol.	**Scan data:** The software can directly acquire images from supported imaging modalities or allow manual import of images by import dialog. The data can be manually adjusted with the wizard editor. The data can be also imported from 3rd party patient management systems via standard protocol – VDDS, or via Nobel Biocare proprietary OPP protocol	**Scan data:** The software can open DICOM 3D images from various device types and producers by import dialog. The data can be manually adjusted with the wizard editor. Scan can be reoriented in 3D coordinates. Stitching of 3D volumes	Same
	Diagnostic: 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	**Diagnostic:** 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	**Diagnostic:** The software allows to review 2D and 3D image data. The user can apply image filters, modify brightness and contrast. The user can apply image filters and can measure length, angles, HU units volumetric measurements of render Comparison of multiple 3D images, 2D intraoral images.	Different – See discussion below

	Visualization of airways, volume segmentation, volume measurement and maximum constriction point determination. Automatic annotation of the mandibular canals based on anatomical landmarks	Visualization of airways, volume segmentation, volume measurement and maximum constriction point determination.	Visualization of airways, volume segmentation, volume measurement and maximum constriction point determination. Creation and visualization of the nerve manually or by using the Automatic Nerve feature	
	Intraoral scanner: Import of surface scan files and their registration with other scans.	**Intraoral scanner:** DTX Studio ioscan module is a user interface supporting a dental optical impression system, more specifically an intraoral scanning device. Review of STL, PLY, NXA type data within dedicated workspace	**Intraoral scanner:** Import of surface scan files and their registration with other scans.	Different – See discussion below
	Automatic sorting algorithm: Intraoral radiograph (IOR) automatic image sorting to an FMX template (dental X-ray image layout).	**Automatic sorting algorithm:** Intraoral radiograph (IOR) automatic image sorting to an FMX template (dental X-ray image layout).	N/A	Same
	Implant Planning: Functionality for implant planning treatment. Adding dental implant shapes to DICOM data for treatment planning.	**Implant Planning:** Functionality for implant planning treatment. Adding dental implant shapes to DICOM data for treatment planning.	**Implant Planning:** Functionality for implant planning treatment. Adding dental implant shapes to DICOM data for treatment planning. Density profile control Abutment planning and margin planning Bone graft simulation	Same

	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	**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	**Virtual tooth setup:** Library of wax-up and prosthetic restorations for crown-down planning Mesh editing and collision detecting features Articulation	Same
Operating system requirements	Windows 10 64-bit, macOS Catalina, macOS BigSur	Windows 10 64-bit macOS Mojave, macOS Catalina	Windows 7 64-bit, Windows 8 64-bit or Windows 10 64-bit., Apple Bootcamp with Windows, macOS Yosemite and higher	Different – See discussion below
Recommended hardware requirements	CPU: quad-core of 2.8 GHz or more (such as Intel Core i5 or i7) RAM: 8GB Graphics card with support of OpenGL 3.3 and 2GB memory or more (4GB or more for 4K displays) HDD: 10GB of free space Monitor: FullHD (1920x1080) or higher	CPU: quad-core of 2.8 GHz or more (such as Intel Core i5 or i7) RAM: 8GB Graphics card with support of OpenGL 3.3 and 2GB memory or more (4GB or more for 4K displays) HDD: 10GB of free space Monitor: FullHD (1920x1080) or higher	CPU: Intel Core i5 2400, recommended Intel Core i7 4000 or similar. RAM min 4GB, recommended 8GB. Graphic card Intel HD 4000, recommended AMD Radeon RX 580 or comparable. HDD: 100 GB minimum, 500 GB recommended.	Same

Discussion

Similarities:
The subject device DTX Studio Clinic 3.0 and primary predicate device DTX Studio Clinic 2.0 (K203156) have the same Intended Use and share most software functions/features. Automatic annotation of the mandibular canals is shared with the reference device InVivoDental (K123519).
As seen in the table above, the subject and predicate devices are equivalent in terms of software functionalities. All devices allow import of variety of 2D/3D imaging data, its enhancement, viewing, processing and visualization for the purpose of supporting the diagnostic and treatment planning process.
Difference in indications for use and software features are discussed below.

Differences:

Indications for Use

The Indications for Use statement between the subject and the primary predicate device (K203156) are the same.

Both DTX Studio Clinic 3.0 and the primary predicate device DTX Studio Clinic 2.0 allow display and enhancement of medical images from various sources, i.e. from various digital imaging systems. In addition, they also allow for retrieving and storage of image data within the system (locally) or across computer systems in distributed locations. DTX Studio Clinic 3.0 allows transfer of images and patient data (store and retrieval) to and from the DTX Studio Core database, thus making the data available in different locations.

Both the subject and primary predicate 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, the subject device allows the user to visualize and evaluate data for the entire craniomaxillofacial area, as a support for the diagnostic process.

Both the subject and primary 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.

Differences in software features/functionality

Input data/Image acquisition - 3D Face scans - The difference between the subject device and the predicate device is that 3D facial scans can now be imported and visualized in the software. 3D Face scans can be used to provide the user with additional information to perform diagnosis and treatment planning.

Diagnostic -Automatic annotation of the mandibular canals - The difference between the subject device and the predicate device is that DTX Studio Clinic 3.0 allows the segmentation and visualization of the mandibular canals. The software automatically segments the mandibular canal based on the identification of the mandibular foramen and the mental foramen. This functionality is similar as in the reference device InVivoDental (K123519). The user can also manually indicate or adjust the mandibular canal.

Intraoral scanner- The difference between the subject device and the predicate device is that the DTX Studio ioscan module, classified as NOF, 872.3661 (510k exempt) is no longer available into the DTX Studio Clinic 3.0. This change does not affect the intended use of the software, since customers can import data from optical intraoral scanners into DTX Studio Clinic 3.0

Minor differences:
Various operating systems are currently supported by DTX Studio Clinic 3.0, due to release of new versions of these operating systems during the lifecycle of DTX Studio Clinic 3.0. DTX Studio Clinic 3.0 was tested and validated on these operating systems

VII. Performance Data

DTX Studio Clinic 3.0 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 standards. 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”.

VIII. Conclusion

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 3.0 is found to be substantially equivalent to the identified Predicate Device.