Nobel Biocare AB
% Vladislavs Mihailovs
Regulatory Affairs Manager
Medicim NV
Stationsstraat 102
Mechelen, Antwerp 2800
BELGIUM

November 20, 2020

Re: K203156
Trade/Device Name: DTX Studio Clinic
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 13, 2020
Received: October 22, 2020

Dear Vladislavs Mihailovs:

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)*
K203156

Device Name
DTX Studio Clinic

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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8. 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: 13 October 2020

II. Device

Name of Device: DTX Studio Clinic
Common or Usual Name: Picture Archiving and Communications System
Classification Name: System, Image Processing, Radiological (21 CFR 892.2050)
Regulatory Class: 2
Product Code: LLZ

III. Predicate Device

Substantial equivalence is claimed to the following device:

Main predicate
Predicate Device: CliniView
Predicate 510(k): K162799
Compay: Palodex Group
Classification name: System, Image Processing, Radiological
Regulatory Class: 2
Regulation number: 892.2050
Product Code: LLZ

Reference device 1:
Predicate Device: DentiqAir
Predicate 510(k): K183676
Compay: 3D Industrial Imaging Co., Ltd
Classification name: System, Image Processing, Radiological
Regulatory Class: 2
Regulation number: 892.2050
Product Code: LLZ

Reference device 2:
Predicate Device: DTX Studio Implant
Predicate 510(k): K163122
Company: Nobel Biocare AB
Classification name: System, Image Processing, Radiological
Regulatory Class: 2
Regulation number: 892.2050
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 and extraoral 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 devices 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 and the predicate device CliniView 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
- Patient data management features

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

- Airway volume segmentation (same with the reference device DentiqAir (K183676))
- Intraoral radiograph (IOR) automatic image sorting to an FMX template
- DTX Studio Clinic ioscan module – a dedicated intraoral scanner workspace for acquisition of 3D intraoral models in STL, NXA, PLY file formats (classification NOF, 872.3661)
- Alignment of intra-oral scan or dental cast scan STL files with (CB)CT data for accurate implant planning (same with the reference device DTX Studio Implant (K163122))
- Scan request – scheduling and reservation of supported imaging modalities for image acquisition. The predicate device CliniView controls settings of imaging modalities for image acquisition, whereas DTX Studio Clinic does not control connected imaging modalities.
- Image data and patient file import from 3rd party Patient Management Systems (PMS)
- Adding dental implant shapes to DICOM data for treatment planning (same with the reference device DTX Studio Implant (K163122))
- Virtual tooth setup – an algorithm for calculation and visualization of a 3D tooth model for missing teeth (same as with the reference device DTX Studio Implant (K163122))

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

Criteria	DTX Studio Clinic (subject device)	CliniView (predicate device) K162799	DentiqAir (reference device for airway segmentation functionality) K183676	DTX Studio Implant (reference device for dental implant planning functionality) K163122	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.	CliniView software program is indicated for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.	DentiqAir is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or CBCT scanners. The dental professionals' planning data may be exported from DentiqAir and used as input data for CAD or Rapid Prototyping Systems.	DTX Studio Implant is a software interface for the transfer and visualization of 2D and 3D image information from equipment such as a CT scanner for the purposes of supporting the diagnostic process, treatment planning and follow-up in the dental and cranio-maxillofacial regions. DTX Studio Implant can be used to support guided implant surgery and to provide design input for and review of dental restorative solutions. The results can be exported to be manufactured.	Different – See discussion below
Classification code	LLZ, NOF	LLZ	LLZ	LLZ	Same
Input data/Image acquisition	DICOM image data volumes, 2D and 3D images such as (CB)CT scans and	2D (CB)CT scans and 2D images such as OPG/ panorex images,	DICOM image data volumes, cephalometric images,	DICOM data from (CB)Ct scanner	Different – See

	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, NXA, PLY files from intraoral and optical scanner.	cephalometric images intra-oral images and clinical pictures	optical impression data visualization		discussion below
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.	Images and related data are stored in the CliniView database or remotely accessible database in the network. Image export	A "Project" consisting of planning data (including segmentation information), volume data, and optical surface data may be exported and imported in a 3DII proprietary format.	Export surgical template design for centralized production in Nobel Biocare facilities. Export surgical template design (proprietary or open format) to be manufactured Export treatment plan for dental restoration design in DTX Studio design	Different – See discussion below

Image processing	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	Enhancement (image filter application), annotations, measurements (distance and angular), import/export and printing.	Image color manipulation tools, view manipulation tools, 3D volume clipping, length and angle measurements, segmentation of anatomical structures, airway segmentation, segmentation of mandible and fossa	Enhancement (image filter application), annotations, measurements (distance and angular). Alignment of intra-oral scan or dental cast scan STL files with (CB)CT data for accurate implant planning.	Different – See discussion below
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 or allow manual import of images by drag and drop or import dialog. The data can be manually adjusted with the panorama curves editor	**Scan data:** Software allow only manual import of images.	**Scan data:** Software allow only manual import of images.	Different – See discussion below
	Diagnostic:	**Diagnostic:**	**Diagnostic:**	**Diagnostic:**	Different – See

	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.	The diagnostic module allows to review and diagnose 2D and 3D (by using 3rd party applications) image data. The user can apply image filters and can measure length, print function, diagnosis The software allows to compare 3D (by using 3rd party applications) images and 2D images in one workspace.	The user can apply image filters and can measure length and angles. Segmentation of anatomical structures.	The user can apply image filters and can measure length, angles and HU units.	discussion below
	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	N/A	N/A	N/A	Different – See discussion below
	Automatic sorting algorithm: Intraoral radiograph (IOR) automatic image sorting to	N/A	N/A	N/A	Different – See discussion below

	an FMX template (dental X-ray image layout).				
	Implant Planning: Functionality for implant planning treatment. Adding dental implant shapes to DICOM data for treatment planning.	N/A	N/A	**Implant planning:** Adding an implant, abutments and anchor pins to a planning. Surgical template calculation from intra-oral surface data.	Different – See discussion below
	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	N/A	N/A	N/A	Different – See discussion below
Operating system requirements	Windows 10 64-bit macOS Mojave, macOS Catalina	Windows 7 Professional/Ultimate/Enterprise SP1 (32 or 64-bit) Windows 8/8.1 Professional/Enterprise (32 or 64-bit) Windows 10	Windows 7,8 and 10(64bit)	PC – Windows based MAC - OS	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	HDD ≥ 8 GB RAM ≥ 4GB CPU Intel Core i3 or better	CPU : Intel i3 Dual Core RAM : 2 GB HDD : 2 GB free space Graphic card that supports DirectX 10.1 Monitor: 1600 x 900 pixels	CPU: dual-core of 3GHz or more RAM: 8GB Graphics card with support of OpenGL 3.3 and 1GB memory or more (2GB or more for 4K displays) HDD: 5GB of free space	Different – See discussion below

	Monitor: FullHD (1920x1080) or higher		resolution	Monitor: FullHD (1920x1080) or higher	

Discussion

Similarities:

The subject device DTX Studio Clinic and primary predicate device CliniView (K162799) have the same Intended Use and share most software functions/features. Other software features such as airway volume segmentation or implant planning are shared with the reference predicate device DentiqAir (K183676) and DTX Studio Implant (K163122). Difference in indications for use and software features are discussed below.

Both softwares utilize a graphic user interface with a large 3D based main window, several dedicated workspaces for various imaging modalities, several visualization and image processing tools for the purpose of facilitating diagnostic and treatment planning process for craniomaxillofacial anatomical area.

Both DTX Studio Clinic and CliniView share functionality of clinical image data import and acquisition from supported devices, data visualization, distance and angular measurements.

Differences:

Indications for Use

The Indications for Use statement between the subject and the primary predicate devices (K162799) are primarily the same. Minor differences in wording do not alter the intended therapeutic use of the subject device.

Both DTX Studio Clinic and the primary predicate device CliniView 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 within the system (locally) or across computer systems at distributed locations. DTX Studio Clinic 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 primary predicate CliniView (K162799) allows to store and retrieve patient data and related image data in a local or central database called Data Warehouse.

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 cranio-maxillofacial area (including the dental area). For this reason, the subject device allows the user to visualize and evaluate data for the entire cranio-maxillofacial area, as a support for the diagnostic process.

One of the differences within the Indications for Use statement is that the subject device can provide design input data for restorative solutions to 3rd party software or software from DTX Studio Ecosystem (DTX Studio Implant and DTX Studio Lab), but it does not provide

functionality of designing restorations within the software itself. Hence, this difference does not impact the therapeutic use of the device.

Another difference in wording within the Indications for Use statement is support of treatment planning. Because diagnostic process naturally leads to a treatment, software contains functionality of storing patient files and their diagnostic history. It is also possible to compare different set of imaging data, for example pre-op and post-op of craniomaxillofacial situation. Because subject device does not contain functionality to signal a necessity of treatment and the decision of treatment planning and execution is taken by the user as a logical outcome of diagnostic process, this difference in wording does not impact therapeutic use of software and it's Intended Use.

Differences in software features/functionality

Airway volume segmentation
Another difference between subject device and the predicate device is that DTX Studio Clinic allows volume segmentation of indicated airway on the image data, volume measurements and constriction point determinations. Such functionality is available in the reference device DentiqAir (K183676).
The difference between the subject device and the reference device is that the latter is intended for segmentation and measurements of various anatomical structures and specifically segmentation of mandible and fossa, while the segmentation and measurements in the subject device are intended and limited to airway.

Automatic image sorting algorithm
In addition, DTX Studio Clinic has an algorithm for automatic sorting of acquired or imported intra-oral X-Ray images. The user has an option to disable this feature. Automatically sorted images are displayed in an FMX layout in software intraoral workspace window. This functionality detects tooth numbers in accordance with either the FDI or the Universal tooth numbering system and sorts it accordingly. This function does not provide any image enhancement or processing capabilities and does not intended to be a part of diagnostic process. This functionality is related to workflow improvement of software, as well as an effective data management tool.

Dedicated software module for intraoral 3D scan acquisition – DTX Studio Clinic ioscan
Another difference from the subject device is an intra-oral workspace and DTX Studio Clinic ioscan module which allows for acquisition of intra-oral surface data using an Intraoral Scanner (IOS) system. It supports a dental optical impression system to record the topographical characteristics of teeth, soft tissue, preparations, scan bodies and existing restorations, or dental impressions or stone models by dental professionals. The resulting three-dimensional (3D) model is intended to be used as part of the digital patient record and design of dental restorations. This module is classified as NOF, 872.3661 (510(k) exempt) and is intended to serve as a CAD/CAM

input for dental restorations. Since this software functionality is 510(k) exempt, this difference does not impact the substantial equivalence between the subject and the predicate devices.

Alignment of intraoral scan with CBCT scan(s)
The subject device DTX Studio Clinic allows import of 3D intraoral models or 3D scans of dental casts for the purpose of aligning them with an imported CB(CT) data for the same patient. This alignment is intended to provide input for accurate implant planning. Same functionality is available in the reference device DTX Studio Implant (K163122)

Scan request
The subject DTX Studio Clinic allows to request scans through DTX Studio Core database by selecting the supported scanner device. CliniView (K162799) controls image capturing of imaging devices for image acquisition and image exposure. Both devices allow for the placing of scan requests and retrieval of scan data. The difference between the subject and the primary predicate is that the predicate software controls the acquisition of scan data including the exposure settings. The subject device allows placing of a scan request where the exposure is set or confirmed, and the scanning started by the operator directly on the scanner. The change in scanner operation does not affect the scan output or the use of the scan data in the software.

Image data and patient file import from 3rd party PMS systems
The subject device DTX Studio Clinic allows import of image data and patient files not only from a native to DTX Studio ecosystem storage and archiving solution (DTX Studio Core), but also from 3rd party PMS systems via VDDS common communication protocol, or via Nobel Biocare proprietary OPP protocol. This difference does not impact the substantial equivalence between the subject and the predicate devices

Implant planning – Another difference between subject device and the predicate device is that DTX Studio Clinic has an implant planning functionality. Such functionality is available in the reference device DTX Studio Implant (K163122).
Implant planning in DTX Studio Clinic allows adding implant shapes to imported 3D data. Position and orientation as well as the implant type and dimensions are defined by user upon adding an implant to imported data. User can enter implant diameter and implant length and visualize the resulting shape on the imported data.

Virtual tooth setup
After importing an intraoral scan, users can calculate a virtual tooth shape for any missing tooth. Where there is a missing tooth, the Virtual Tooth setup algorithm calculates a 3D tooth shape based on the captured intraoral scan. This 3D calculated tooth shape is then used for prosthetic visualization purposes for patient communication or as input for defining implant position. The calculated virtual tooth is visualized in the 3D scene. This visualization can be used for patient communication or as input for defining the preferred implant position.

Minor differences:
Various operating systems are currently supported by DTX Studio Clinic, due to release of new versions of these operating systems during the lifecycle of DTX Studio Clinic. Also, with the advancement of computer hardware technologies and increase in resolution of modern monitors, recommended hardware requirements for computers were adjusted accordingly.
DTX Studio Clinic was tested and validated on all these operating systems and hardware variations.

VII. Performance Data

DTX Studio Clinic 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 EN IEC 62304:2006 standards. Design Control Activities, including risk management following the ISO 14971:2012, 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.

No clinical data was used to support the decision of substantial equivalence.

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