January 11, 2018

Nobel Biocare AB
% Charlemagne Chua
Senior Regulatory Affairs Manager
Nobel Biocare USA LLC
22715 Sasvi Ranch Parkway
Yorba Linda, California 92887

Re: K172224
Trade/Device Name: DTX Studio diagnose
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 13, 2017
Received: December 14, 2017

Dear Charlemagne Chua:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172224

Device Name
DTX Studio diagnose

Indications for Use *(Describe)*

DTX Studio diagnose is a software program for the transfer and visualization of dental and craniomaxillofacial image information. It displays and enhances digital images from various sources to support the diagnostic process. It stores and communicates these images within the system or across computer systems at distributed 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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A.4. 510(k) Summary

I. SUBMITTER

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Submitted by
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22715 Savi Ranch Parkway
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Date Prepared: December 12, 2017

II. DEVICE

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

III. PREDICATE DEVICE

Primary predicate:
Palodex Group Oy – Cliniview (K162799)

Reference predicate:
Sirona Dental Systems – Sidexis 4 (K132773)

IV. DEVICE DESCRIPTION

DTX Studio diagnose is a software solution used to support the image-based diagnostic process of dental and cranio-maxillofacial cases.

DTX Studio diagnose has specific functionalities to visualize imaging information for facilitating diagnosis, e.g. 2D and 3D X-ray information, and to perform specific measurements on the data to support users with the diagnostic process.

The types of digital image data which are supported by the DTX Studio diagnose include, for example, 3D (CB)CT images, orthopantomograph(OPG)/panorex images, intraoral images, cephalograms and clinical pictures.

DTX Studio diagnose allows the user to view and inspect the patient images, and to add findings and measurements. Indicated findings can be saved within the patient profile in DTX Studio. For the purposes of diagnosis, different workspaces are available within the diagnostic module.

The DTX Studio diagnose software is compatible with both Windows and Mac OS X operating systems. Two different software versions/installers are available based on the user's operating system.

V. INDICATIONS FOR USE

DTX Studio diagnose is a software program for the transfer and visualization of dental and craniomaxillofacial image information. It displays and enhances digital images from various sources to support the diagnostic process It stores and communicates these images within the system or across computer systems at distributed locations.

VI. Comparison of Technological Characteristics

Technological characteristics	SUBJECT	Primary Predicate	Reference Predicate	Comments
	DTX Studio diagnose	*Cliniview (K162799)*	*Sidexis 4* (K132773)	*Except as noted comparison is made to the primary predicate*
Trade name	DTX Studio diagnose	Cliniview	Sidexis 4	
FDA product code	LLZ	LLZ	LLZ	Same
Classification	Class II	Class II	Class II	Same
Indications for use / Intended Use	DTX Studio diagnose is a software program for the transfer and visualization of dental and craniomaxillofacial image information. It displays and enhances digital images from various sources to support the diagnostic process It stores and communicates these images within the system or across computer systems at distributed 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.	SIDEXIS 4 is software that offers functions for the acquisition, administration, analysis, diagnosis, presentation and transfer of digital or digitized image data, e.g. X-ray images or video recordings, for medical use, predominantly in dentistry.	Different – See discussion below
Input data/ Image acquisition	2D and 3D images such as (CB)CT scans and 2D images such as OPG/ panorex images, cephalometric images intra-oral images and clinical pictures	2D (CB)CT scans and 2D images such as OPG/ panorex images, cephalometric images intra-oral images and clinical pictures	2D and 3D images such as (CB)CT scans and 2D images such as OPG/ panorex images, cephalometric images intra-oral images and clinical pictures	Same as reference predicate
Image processing functionality	Enhancement, annotation, measurement, import/export.	Enhancement, annotation, measurement, import/export and printing.	Enhancement and presentation, import/export	Same

Technological characteristics	SUBJECT	Primary Predicate	Reference Predicate	Comments
	DTX Studio diagnose	*Cliniview (K162799)*	*Sidexis 4* (K132773)	*Except as noted comparison is made to the primary predicate*
Output data	Data is stored locally or in remotely accessible database in the network (DTX core)	Images and related data are stored in the Cliniview database or remotely accessible database in the network. Image export	2D Views/images export to specified location or via e-mail DICOM exam/report/volume export Facescan OBJ export Image and workspace printing	Same
Software features	The software provides several workspaces to review the images. It provides specific workspaces to review (a selection of) the imported images like e.g. full mouth series template for intraoral images, and it provides workspaces to review a specific set of images to support diagnosis of a selected area combining several image types.	A workspace is available to work with imported images. It is also possible to load and view 3D images or multilayer pan images by using 3rd party software.	The software provides several layouts to review the images. It provides specific layout to review (a selection of) the imported images like e.g. full mouth series template for intraoral images.	Same as reference predicate
	Access images from DTX core database or allow manual import	Access images from database or allow manual import	Acquire images from x-ray devices or allow manual import	Same
	Scan requests creation for image acquisition	Image acquisition from connected devices	X-ray exposure creation to request image acquisition	Different – See discussion below
	2D and 3D data visualization	2D data visualization Cliniview is able to send 2D and 3D images to 3rd party viewers and is also able to receive patient information from 3rd party patient management software	2D and 3D data visualization	Same as reference predicate

Technological characteristics	SUBJECT	Primary Predicate	Reference Predicate	Comments
	DTX Studio diagnose	*Cliniview (K162799)*	*Sidexis 4* (K132773)	*Except as noted comparison is made to the primary predicate*
	Adjust patient positioning in the software and optimize cross-sections and projected images	Not available	Adjust data with the panorama curves editor	Same as reference predicate
	Apply image filters, make annotations	Apply image filters, make annotations	Apply image filters, make annotations	Same
	Length and angles measurement	Length, angle and free angle measurements	Length and angles measurement	Same
System Requirements	Workstation: Operating System: Windows® 7, 8.1, 10 (64 bit), Mac OS® X (Yosemite, El Capitan); Mac OS® Sierra HDD ≥ 5 GB of free disk space RAM ≥ 8 GB CPU ≥ 2.8 GHz QuadCore Graphic Card ≥ 2 GB Screen Full HD (1920 x 1080) or higher	Workstation PC: Operating system: Windows 7 Professional/Ultimate/Enterprise SP1 (32 or 64-bit) Windows 8/8.1 Professional/Enterprise (32 or 64-bit) Windows 10 HDD ≥ 8 GB RAM ≥ 4GB CPU Intel Core i3 or better	Workstation PC: Operating System: Windows 7 Pro SP1 (32 o. 64 bit) Windows 8.1 Pro (64 bit) Windows 10 Pro (64 bit) HDD ≥ 5 GB RAM ≥ 4 GB CPU ≥ 2 GHz DualCore Graphic Card ≥ 512 MB Screen 1280 x 1024 Pixel	Different – See discussion below

Analysis of Differences Between Subject Device and Predicates

The subject device DTX Studio diagnose and primary predicate Cliniview (K162799) have the same intended use and share most software features. Other software features are shared with the reference predicate Sidexis 4 (K132773). Differences in indications for use and software features are discussed below.

Indications for Use/ Intended 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 diagnose and the primary predicate Cliniview (K162799) 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 diagnose allows transfer of images and patient data (store and retrieval) to and from the DTX 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.

Software features

Scan request - The subject DTX Studio diagnose allows to request scans through DTX core by selecting the scanner device, e.g. 3D scan or OPG / panorex. 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.

System requirements – The subject device DTX Studio diagnose is available for both Windows and Mac OS X operating systems. The primary predicate Cliniview (K162799) is only available for the Windows operating system. This change is supported by verification and validation testing conducted on both operating systems.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing:

The performance of the subject device was verified and validated following the guidance provided in FDA Guidance General Principles of Software Validation", issued on January 11, 2002. This documentation includes testing which demonstrates that the requirements for the features have been met. Software Documentation for a Moderate Level of Concern, 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.

VIII. CONCLUSIONS

The DTX Studio diagnose was evaluated for substantial equivalence using standard testing. Based on technological characteristics and non-clinical test data included in this submission, the DTX Studio diagnose was shown to be substantially equivalent to the Cliniview software (K162799).