March 1, 2019

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

Re: K181932
Trade/Device Name: DTX Studio design
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP, NHA
Dated: January 24, 2019
Received: January 28, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181932

Device Name
DTX Studio design

Indications for Use *(Describe)*

DTX Studio design software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. DTX Studio design software is intended to be used by dental laboratory staff or a dental practitioner for designing patient specific component of a two-piece, one-piece or hybrid dental implant abutment. The single or multiple patient specific abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

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)*

K181932 510(k) Summary

I. Submitter

Submitted by:

Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Contact Person: Charlemagne Chua
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Submitted for:

Nobel Biocare AB
Vastra Hamngatan 1
Goteborg, SE-411 17
Sweden

Date prepared: 03/01/2019

II. Device

Device Proprietary Name:	
Trade name:	DTX Studio design
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Primary Product Code:	PNP (Dental Abutment Design Software for Dental Laboratory)
Secondary Product Code :	NHA (Endosseous Dental Implant Abutment)
Device Classification	2

III. Predicate/Reference Devices

Substantial equivalence is claimed to the following predicate devices:

- Primary Predicate:
  - 3Shape Abutment Designer Software K151455
- Reference Predicate
  - DTX Studio design K171466

IV. Device Description

DTX Studio design* is a stand-alone software platform that integrates CAD software to render a design of a dental abutment. The software receives surface scan data containing topographical characteristics of real teeth, position and orientation of implants and uses also an integrated third-party software to

perform the CAD design of the dental abutment. Additional functions include creating and tracking cases. The output of the device is a computer file containing the dental abutment in a digital form. *Note: DTX Studio design will transition to a new name and will also be known as DTX Studio Lab.

In accordance with the classification of the dental abutment and the related 510k clearance, the output file can be sent to an FDA registered facility or can be used by 3rd party providers to manufacture the physical dental abutment based on their 510(k) product clearance.

The following functionality was added compared with the previously cleared DTX Studio design (K171466) software:

- Allow the user to design and order a NobelProcera Bar;
- Extension of the function to import STL files from different scan sources;
- Dental abutments may be produced from scan data from 3rd party scanners for centralized production;
- Dental abutment design requests including intraoral scan data, can be received in DTX Studio design from a clinician;
- Implementation of verified and validated prosthetic libraries provided by 3rd parties to allow design and export for localized production.
  These libraries contain a number of design parameters and product constraints, such as connection geometry, minimum thickness, titanium base, implant lab analog, screw channel angle, maximum angulation for abutments/2-piece abutment/ hybrid crown, abutment post height above implant collar;
- Export of digital design file (.STL) for dental implant abutment (per 872.3630, NHA) for local production of patient-specific abutment components.

DTX Studio design is programmed in C++ and can be run on standard consumer PC running Windows 64bit.

V. Indications for Use

DTX Studio design software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. DTX Studio design software is intended to be used by dental laboratory staff or a dental practitioner for designing patient specific component of a two-piece, one-piece or hybrid dental implant abutment. The single or multiple patient
specific abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

VI. Comparison of Technological Characteristics

	Subject Device DTX Studio design	**Primary Predicate 3Shape Abutment Designer Software K151455**	**Reference Predicate DTX Studio design K171466**	**Notes**
Indications For Use	DTX Studio design software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. DTX Studio design software is intended to be used by dental laboratory staff or a dental practitioner for designing patient specific component of a two-piece, one-piece or hybrid dental implant abutment. The single or multiple patient specific abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	The software is intended to be used at a dental clinic or a dental laboratory. The software uses patient-specific data from scanners, e.g. a scanned geometry, and facilitates the CAD of individual restorative solutions based on these data, such as a supporting dental framework, dental abutments, copings, crowns, and bridges. The software also serves as a means of creating and managing of cases, and the ordering of products.	Equivalent to primary predicate. Patient specific is added since the software is used to design customized dental abutments, based on the patient anatomy.
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same
Regulation Name:	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same
Regulatory Class	2	2	2	Same
Products Code*	PNP, NHA	PNP	NHA, NOF	See note below.
Intended user	Dental practitioner or dental laboratory staff	Dental practitioner or dental laboratory staff	Dental practitioner or dental laboratory staff	Same
Features				
Case management	Yes	Yes	Yes	Same
Scan module	Yes	Yes	Yes	Same
CAD Design module	Yes	Yes	Yes	Same
Order module	Yes	Yes	Yes	Same
User interface	Workspace with 3D model	Workspace with 3D model	Workspace with 3D model	Same

	Subject Device DTX Studio design	**Primary Predicate 3Shape Abutment Designer Software K151455**	**Reference Predicate DTX Studio design K171466**	**Notes**
Wizards	Yes	Yes	Yes	Same
Visualization tools	Yes	Yes	Yes	Same
Safety limitations	Yes (warning and/or hard block)	Yes (warning and/or hard block)	Yes (warning and/or hard block)	Same
Configuration and settings	Controlled availability of products, based on the country of the user and the regulatory status.	Locked libraries for US	Controlled availability of products, based on the country of the user and the regulatory status.	Same as reference predicate
User able to modify libraries	No	No	No	Same
Input	Desktop and intraoral scanners	Desktop and intraoral scanners	Desktop and intraoral scanners	Same
Output	Computer file containing CAD model	Computer file containing CAD model	Computer file containing CAD model	Same
Device includes pre manufactured prosthetics (per 872.3630)	No	No	No	Same
Milling location	Abutment Manufacturer or Dental laboratory per the 510k clearance of the dental abutment	Abutment Manufacturer or Dental laboratory per the 510k clearance of the dental abutment	Nobel Biocare	Same as primary predicate
CAD Indications				
Customized abutment	Yes	Yes	Yes	Same
Anatomical abutment	Yes	Yes	Yes	Same
Screw retained abutment	Yes	Yes	Yes	Same
Wax up abutment**	Yes	Yes	Yes	Same
Implant bridge design	Yes	Yes	Yes	Same
Consumables				
Nobel Biocare prosthetic libraries	Yes	Yes	Yes	Same
3rd party prosthetic libraries	Yes	Yes	No	Same as primary predicate
CAD tools				
Measurement tool	Yes	Yes	Yes	Same
Align meshes	Yes	Yes	Yes	Same
Annotations	Yes	Yes	Yes	Same

	Subject Device DTX Studio design	**Primary Predicate 3Shape Abutment Designer Software K151455**	**Reference Predicate DTX Studio design K171466**	**Notes**
Virtual articulator	Yes	Yes	Yes	Same
Screenshot tool	Yes	Yes	Yes	Same

Notes:

* Changes to subject software include both local and centralized milling of dental abutments, therefore PNP and NHA are included

**The design of a wax up abutment starts from an initial shape based on a scan of a wax model (created using a wax up technique). The abutment design is then further optimized within DTX Studio design using CAD tools.

VII. Discussion

The Indications for Use between the subject and the primary predicate devices are equivalent and the minor differences are to provide more clarity to the user, but do not alter the intended clinical use of the subject device.
DTX Studio design and the predicate 3Shape Abutment Designer Software are both standalone software used for the CAD design of dental abutments. Both software utilize a graphic user interface with a large 3D based main window, several visualization tools and implement a system of wizards that guide the user through all steps of the workflows.
DTX Studio design and the predicate include similar tools for the management of patient cases and for tracking the orders, can import of surface scan data and use proprietary file formats (for supporting specific desktop scanners), and can import an open file format.
DTX studio design provides similar CAD tools to design the same types of dental abutments available in the predicate 3Shape Abutment Designer. If the dental abutment design exceeds the safety limits, the user can experience a warning and a “hard stop”, meaning that the user cannot continue designing, in the subject and predicate devices. Both devices do not allow end-users changing the implant settings or safety limits in the libraries.
Both devices are capable of exporting the digital design to be used for manufacturing of the physical device, either by means of a proprietary format or an open format, such as the STL format.

VIII. Performance Data

DTX Studio design is designed and manufactured under the Quality System Regulations as outline 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.

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