March 28, 2023

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

Re: K221921
Trade/Device Name: DTX Studio Clinic 3.0
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: February 24, 2023
Received: February 27, 2023

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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)*
K221921

Device Name
DTX Studio Clinic 3.0

Indications for Use *(Describe)*
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 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) Summary

I. Submitter

Submitted by:
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Vastra Hamngatan 1
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Establishment Registration No. 9611992
Date Prepared: March 28, 2023

II. Device

Name of Device: DTX Studio Clinic 3.0
Manufacturer: Nobel Biocare AB
Common or Usual Name: Medical Image Analyzer
Regulation Number: 21 CFR 892.2070
Classification Name: Medical Image Analyzer
Product Code: MYN
Device Class: II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:
Predicate Device: Videa Caries Assist
Predicate 510(k): K213795
Company: Videa Health, Inc
Common or Usual Name: Medical Image Analyzer
Regulation Number: 21 CFR 892.2070
Classification Name: Medical Image Analyzer

Product Code: MYN
Device Class: II

Secondary Predicate:
Predicate Device: Second Opinion
Predicate 510(k): K210365
Company: Pearl Inc.
Common or Usual Name: Medical Image Analyzer
Regulation Number: 21 CFR 892.2070
Classification Name: Medical Image Analyzer
Product Code: MYN
Device Class: II

IV. Device Description

DTX Studio Clinic features an AI-powered Focus Area Detection algorithm which analyzes 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.

V. Indications for Use

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 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.

VI. Substantial Equivalence

Comparing indications:

DTX Studio Clinic 3.0 and the predicate devices (Videa Caries Assist (K213795) and Second Opinion (K210365)) all analyze dental intraoral radiographs and annotate suspected areas of interest for the dentist to review. Both DTX Studio Clinic 3.0 and the primary predicate, Videa Caries Assist perform concurrent detection of dental findings. DTX Studio Clinic identifies four types of dental findings: caries, apical lesions (periapical radiolucency), root canal defect, marginal defect (discrepancy at the margin), bone loss and calculus, while the primary predicate, Videa Caries Assist, only identifies caries. However, the secondary predicate, Second Opinion, also identifies four different types of dental findings: identifies 4 types of dental findings, caries, discrepancy at the margin, calculus, and periapical radiolucency. Although the pathological dental findings differ, they all share the same intended use, as they are all computer-assisted detection devices that accept dental radiographs as inputs and use supervised machine learning to identify and highlight ROIs. The subject device, is intended for a patient population of patients from the age of 15 years where as the primary predicate, Videa Caries Assist is intended only for intraoral radiographs of patients older than 22 years. The secondary predicate, Second Opinion is intended for a patient population of patients from the age of 12 years. Both DTX Studio Clinic and Second Opinion support the dentist on the review of both bitewing and periapical radiographs. The differences in Indications for Use do not constitute a new indented use, as the subject and primary predicate are both intended to assist the dentist by identifying suspected areas of interest in intraoral radiographs

Technical comparisons

The comparison of the technological features of DTX Studio Clinic and the predicate devices can be found in table 1.

Table 1: Comparison of DTX Studio Clinic to Predicate Devices

Criteria	DTX Studio Clinic 3.0 (Subject Device) (K221921)	Videa Caries Assist Predicate Device (Primary) (K213795)	Pearl - Second Opinion Secondary Predicate Device (K210365)	Comments
Regulatory Information				
Regulation #	892.2070	892.2070	892.2070	Same
Classification Name	Medical Image Analyzer	Medical Image Analyzer	Medical Image Analyzer	Same
Device Class	II	II	II	Same
Product Code	MYN	MYN	MYN	Same
Indication for Use / Intended Use				
Indications for Use Statement	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	Videa Caries Assist is a computer-assisted detection (CADe) device that analyzes intraoral radiographs to identify and localize carious lesions. Videa Caries Assist is indicated for use by board licensed dentists for the concurrent review of bitewing (BW) radiographs	Second Opinion® is a computer aided detection ("CADe") software to identify and mark regions in relation to suspected dental findings which include Caries, Discrepancy at the margin of an existing restoration, Calculus, Periapical radiolucency, Crown	Similar to Primary Predicate, except for some additional dental findings and age of patient population. Patient population is same as the Secondary Predicate, but the differences do not raise a concern of substantial

	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.	acquired from adult patients aged 22 years or older.	(metal, including zirconia & non-metal), Filling (metal & non-metal), Root canal, Bridge and Implants. It is designed to aid dental health professionals to review bitewing and periapical radiographs of permanent teeth in patients 12 years of age or older as a second reader.	equivalence as demonstrated by performance testing
Technological Characteristics				
Focus Area Detection	**Automated Detection Output** Message indicating if and how many dental findings are detected Set of togglable bounding boxes around suspected dental findings	**Automated Detection Output** Message indicating if and how many carious lesions were detected. Set of togglable bounding boxes around suspected lesions	**Automated Detection Output** Bounding boxes	Same as Primary Predicate
	Dental Findings Caries, periapical radiolucency, root	**Dental Findings** Caries	**Dental Findings** Caries, discrepancy at the margin, calculus,	Similar to Predicate Devices, additional dental findings are

	canal filling deficiency, discrepancy at the margin of an existing restoration, bone loss and calculus		and periapical radiolucency	identified but the differences do not raise a concern of substantial equivalence as demonstrated by performance testing.
	Reader workflow Concurrent Reading	**Reader workflow** Concurrent Reading	**Reader workflow** Second reader	Same as Primary Predicate
	Algorithm Supervised machine learning	**Algorithm** Supervised machine learning	**Algorithm** Supervised machine learning	Same
	Patient population Permanent teeth in patients 15 years of age or older	**Patient population** Adults ≥ 22 years	**Patient population** Permanent teeth in patients 12 years of age or older	Similar to Predicate Devices, the differences do not raise a concern of substantial equivalence as demonstrated by performance testing.
	Radiographs Bitewing and Periapical	**Radiographs** Bitewing	**Radiographs** Bitewing and Periapical	Same as Secondary Predicate, the differences do not raise a concern of substantial equivalence as demonstrated by performance testing.
Intended user	Dentists	US license dentists	Dentists	Same

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+A1:2015 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 verification and validation 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".

Standalone Performance

A standalone performance assessment was conducted to measure the performance of the AI-powered Focus Area Detection algorithm by itself, in the absence of any interaction with a dentist. A separate dataset of 452 adult IOR images including both bitewings and periapical radiographs, was assembled. The dataset was ground-truthed by a group of 10 dental practitioners followed by an additional expert review. In total the data set contained 1767 dental findings (365 caries, 110 periapical radiolucencies, 145 root canal filling deficiencies, 216 discrepancies at restoration margins, 588 bone loss instances and 343 calculus instances).

The standalone overall sensitivity was found to be 0.79 (with 95% CI [0.74, 0.84]), standalone sensitivity per dental finding type is listed in Table 2. Overall precision was found to be 0.45 (with 95% CI [0.40, 0.50]). The standalone localization accuracy was studied by measuring the intersection over union (IoU) and the Dice score (see Table 2) of the detected findings. Mean Dice score was found to be in range of 53.5% to 71.9%, indicating a high overlap between the AI detected findings and the ground truth annotations.

DENTAL FINDING TYPE	SENSITIVITY	MEAN IOU (%)	MEAN DICE (%)
CARIES	0.70 [0.65, 0.75]	58.6 [56.2, 60.9]	71.9 [69.9, 74.0]
PERIAPICAL RADIOLUCENCY	0.68 [0.59, 0.77]	48.9 [44.9, 52.9]	63.7 [59.9, 67.5]

ROOT CANAL FILLING DEFICIENCY	0.95 [0.91, 0.99]	51.9 [49.3, 54.6]	66.9 [64.3, 69.4]
DISCREPANCY AT RESTORATION MARGIN	0.82 [0.77, 0.87]	48.4 [46.0, 50.7]	63.5 [61.3, 65.8]
BONE LOSS	0.78 [0.75, 0.81]	44.8 [43.4, 46.3]	60.1 [58.7, 61.6]
CALCULUS	0.80 [0.76, 0.84]	55.5 [53.7, 57.3]	70.1 [68.4, 71.7]

Table 2: Standalone performance results of the Focus Area Detection algorithm for the 6 dental finding types. For each measure the 95% CI range is listed.

Clinical Performance Assessment

A retrospective fully crossed, multi reader, multi case study was performed to demonstrate that the aid of IOR Focus Area Detection algorithm increases the diagnostic detection and localization performance of dentists for dental findings in IORs. The primary endpoint was a significant Area Under the Curve (AUC) increase in the study arm compared to the control arm. The AUC figure of merit value was obtained based on an AFROC (Alternative Free Response Receiver Operating Characteristic) curve analysis.

The dataset contains 216 periapical and bitewing IOR images that were acquired in US-based dental offices by either sensor or photostimulable phosphor plates. The images were obtained from both male (43%) and female (42%) patients with ages ranging between 15 and 93 years (average age 49.4). The ground truth was defined by 4 ground truthers with a 3 out of 4 consensus. All ground truthers have at least 20 years of experience in reading of dental x-rays.

The IORs were read by 30 readers in a fully crossed design, with half of the readers starting with unaided reading and the other half with aided reading by the support of the AI introduced to DTX Studio Clinic 3.0. After a wash-out period of 4 weeks, the reader groups were swapped, and reading was repeated.

The analysis showed the increase of the AUC from the control arm to the study arm to be highly significant ($p<0.001$), with an overall increase for all dental finding types together of 8.7% (CI [6.5, 10.9]). The breakdown of the AUC difference per dental finding (secondary endpoints) showed a significant increase for the aided reading for all dental findings compared to the unaided reading. In detail, an increase of 13.5% for root canal filling deficiency, 10.2% for periapical radiolucency, 10.1% for discrepancy at margin of an existing restoration, 7.2% for calculus, 6.1% for caries, and 5.6% for bone loss. The improvement in aided reader performance versus unaided reader performance was moreover seen for each of the 30 readers.

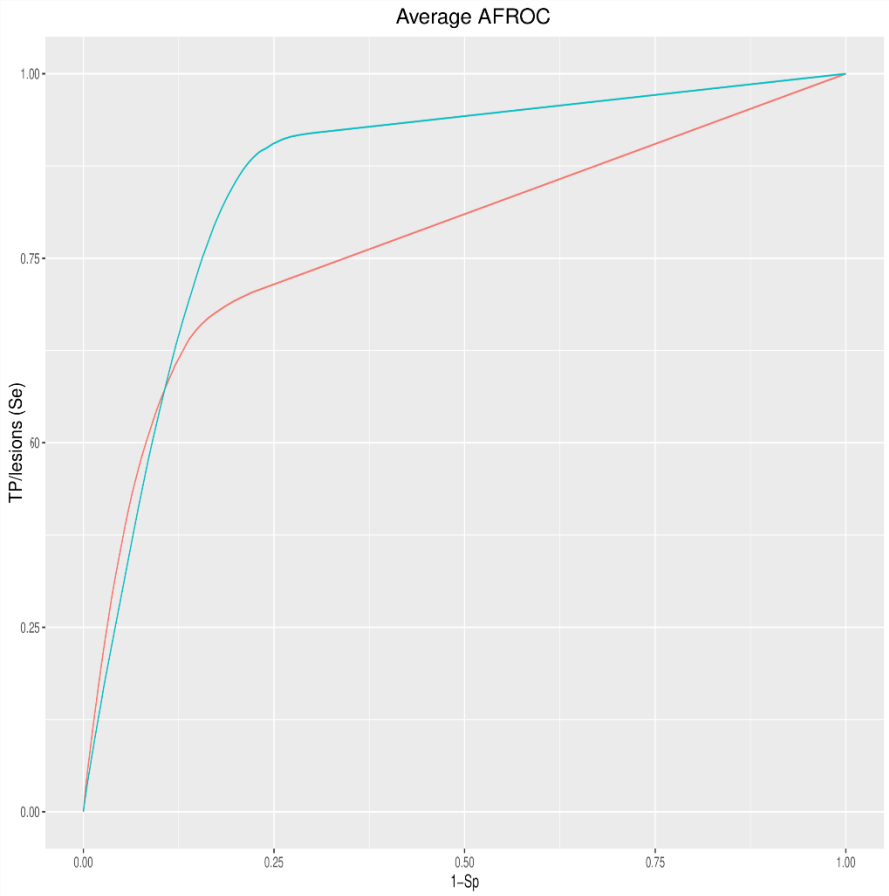

Figure 1: Averaged, interpolated AFROC curve summarizing the overall detection performance. (Control arm in red, Study arm in blue)

Sensitivity on instance level, i.e. the reader's ability to detect existing dental findings, improved substantially for aided reading compared to unaided reading: overall by 22.4% (with CI [20.1, 24.7]), as well as for each dental finding type separately: 19.6% for caries, 23.5% for bone loss, 18.1% for calculus, 28.5% for discrepancy at restoration margin, 20.6% for periapical radiolucency and 27.4% for root canal filling deficiency. A mild decrease in specificity at image level was observed for the aided reading when compared to unaided reading (overall by 8.7 % with CI [6.6, 10.7]).

VIII. Conclusion

The predicate and the subject device have the same intended use as they are both computer-assisted detection devices that accept dental radiographs as inputs and use supervised machine learning to identify and highlight dental findings. Although there are technological differences, as discussed above, these differences do not raise different questions of safety and effectiveness, as overall functionality as a reading aid for radiographs and utility within the

associated clinical workflows offered to the dental professional by the subject and predicate are the same.

Software testing verified the device functioned as intended. The results of the Clinical Performance Assessment demonstrate that the performance of DTX Studio Clinic 3.0 is comparable to that of Videa Caries Assist (K213795). Therefore DTX Studio Clinic 3.0 can be found substantially equivalent to Videa Caries Assist (K213795).