November 21, 2023

Software Nemotec S.L.
% Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, Colorado 80127

Re: K232549
Trade/Device Name: NemoCast
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: August 23, 2023
Received: August 23, 2023

Dear Kevin Walls:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232549

Device Name

NemoCast

Indications for Use *(Describe)*

NemoCast is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. It can also be applied during the treatment to inspect and analyze the progress of the treatment.

The use of the NemoCast requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

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 - K232549

This summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Information:

Software Nemotec S.L.

Av. Juan Caramuel, Nº1

Leganés, Madrid, Spain, 28919

Submission Correspondent:

Kevin Walls
Principal Consultant, Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, Colorado 80127

Device Information:

Trade Name:	NemoCast
Common Name:	Orthodontic Software
Classification Name:	Orthodontic Plastic Bracket
Classification Regulation:	21CFR 872.5470
Device Class:	II
Product Code:	PNN, LLZ

Reference Device:

NemoCast, Software Nemotec, K193003

Primary Predicate:

3Shape Ortho System™, 3Shape A/S, K152086

Date Prepared:

Aug 08, 2023

Predicate Device:

The NemoCast Software has the same intended uses and technical characteristics as primary predicate 3Shape Ortho System™ (K152086) from 3Shape A/S and reference predicate NemoCast from Software Nemotec (K193003) as listed in the table below:
Based on the information and supporting documentation provided, the NemoCast Software and the primary predicate (3Shape Ortho System™) have the same intended use.
Both software devices are used by Dental Professionals in orthodontic treatment planning (before, during, after treatment) covering management of patients and models, inspection, 2D and 3D measurement and orthodontic analysis of models, 2D & 3D treatment simulation, as well as virtual appliance preparation, handling and export, and they are both providing device output. Additionally, the indirect bonding functionality of both systems is intended for use with commercially available brackets and wires. Therefore, the NemoCast Software and the primary predicate (3Shape) are found to be similar in their intended use, supported anatomic areas and the majority of the available features and functionalities.

Device Description:

NemoCast is a software system used for the management of 3D scanned orthodontic models of the patients, orthodontic diagnosis by measuring, analyzing, inspecting and visualize 3D scanned orthodontic models, virtual planning of orthodontic treatments by simulating tooth movements, virtual placement of orthodontic brackets on the 3D models and design of orthodontic appliances based on 3D scanned orthodontic models, including transfer methods for indirect bonding of brackets. Output includes STL Models (also called dental casts) for thermoforming aligners, STL files for direct printing aligners and Indirect Bonding Transfer Trays (also called orthodontic bracket placement trays). The device has no patient contact.

Indications for Use:

NemoCast is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. It can also be applied during the treatment to inspect and analyze the progress of the treatment.

The use of the NemoCast requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

NEMOTEC
A BIOTECH DENTAL COMPANY

Comparison of Intended Use and Technological Characteristics with the reference Device:

Substantial Equivalence Table				
Feature name	**SUBJECT DEVICE** NemoCast	**REFERENCE DEVICE** NemoCast (K193003)	**PRIMARY PREDICATE** 3Shape Ortho System ™, K152086	**Differences**
Product Code	PNN, LLZ	PNN, LLZ	PNN, LLZ	None
Common Name	Orthodontic Software	Orthodontic Software	Orthodontic Software	None
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	None
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	None
Supported anatomic areas	Maxilla and Mandible	Maxilla and Mandible	Maxilla and Mandible	None
Intended Use				
Use by dental professionals in orthodontic treatment planning (before, during, after treatment).	Yes	Yes	Yes	Reference device NemoCast was used by dental professionals only before treatment.
Management of patients and models.	Yes	Yes	Yes	None
Inspection, measurement and analysis of orthodontic models.	Yes	Yes	Yes	None
Treatment simulation.	Yes	Yes	Yes	None
Virtual appliance preparation (including dental casts), handling and export.	Yes	Yes	Yes	None
Provide digital file and device output.	Yes	Yes	Yes	All 3 devices output STL files for fabrication of dental casts. The subject Device and predicate Device

				both additionally output indirect Bonding Transfer Media.
Supported PC formats	**Windows**	**Windows**	**Windows**	None
Managing patient and case base data:				
Creating, editing, deleting and copying patient data	Yes	Yes	Yes	None
Creating, editing, deleting and copying case data	Yes	Yes	Yes	None
Collection of study material				
Surface scan from intra-oral scanner	Yes	Yes	Yes	None
Surface scan from STL, PLY, OBJ file	Yes	No	Yes, only STL	Although predicate device only import STL format, the OBJ and PLY formats are other equivalent formats which do not affect the security and safety of the device.
CT image data	DICOM	DICOM	DICOM	None
2D overlay	PNG, JPG, BMP	PNG, JPG, BMP	PNG, JPG, BMP	None
Alignment of study material				
Aligning surface scan and CT image	Yes	Yes	Yes	None
Aligning cephalometric images	Yes	Yes	Yes	None
Alignment of surface scan with 2D overlays	Yes	Yes	Yes	None
Ability to check/adjust DICOM visibility	Yes	Yes	Yes	None
DICOM scan segmentation	Yes	Yes	Yes	None
Occlusal Orientation	Yes	Yes	No	Although the predicate device does not perform occlusal

				orientation, the reference device contains this option.
Segmenting teeth roots	Yes	Yes	No	Although the predicate device does not segment teeth roots, the reference device contains this option.
DICOM orientation	Yes	Yes	Yes	None
Measuring study material				
2D measurement toolbox	Yes	Yes	Yes	None
3D measurement toolbox	Yes	Yes	Yes	None
Analyzing study material				
Arch shape	Yes	Yes	Yes	None
Wire length	Yes	Yes	Yes	None
Tooth width	Yes	Yes	Yes	None
Bolton	Yes	No	Yes	None
Space analysis	Yes	Yes	Yes	None
Overjet/overbite	Yes	No	Yes	None
Occlusion map	Yes	Yes	Yes	None
Treatment analysis and report generation	Yes	Yes	Yes	None
Treatment simulation				
2D & 3D simulation	Yes	Yes	Yes	None
Virtual appliance design				
Orthodontic appliance search	Yes	Yes	Yes	None
Orthodontic appliance virtual preparation	Yes	Yes	Yes	None
Orthodontic appliance design	Yes	Yes	Yes	None
Orthodontic appliance export	Yes	Yes	Yes	None
Virtual articulator	Yes	Yes	Yes	None

Indications for Use	NemoCast is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, **Indirect Bonding Transfer Media**) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome	NemoCast is intended for supporting the diagnostic and treatment plan processes for orthodontic procedures related to minor anterior tooth movements; it provides tools for management of orthodontic models, systemic inspection, detailed analysis, treatment simulation and virtual appliance design options (export of models) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied to evaluate if the outcome is consistent with the planned/desired treatment objectives. NemoCast requires the user to have	3Shape Ortho System™ is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Custom Metal Bands, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with	The indications for use for the 3 devices are the same, with the exception of the virtual design options. (Compared to the reference device, the Subject Device additionally is used for design of Indirect Bonding Transfer Media. The Subject Device virtual design options are the same as the Virtual design options for the predicate Device.)

	is consistent with the planned/desired treatment objectives. It can also be applied during the treatment to inspect and analyze the progress of the treatment. The use of the NemoCast requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	the planned/desired treatment objectives. The use of the Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	
Intended User	Dental Professionals	Dental Professionals	Dental Professionals	None
Intended Patient Population	Patients requiring Orthodontic Treatment	Adults requiring Orthodontic Treatment	Patients requiring Orthodontic Treatment	The intended patient population for the subject device is the same as the predicate device. The reference device intended patient population was only for Adults.

TECHNOLOGICAL CHARACTERISTICS

NemoCast; Software Nemotec, is software for simulating/evaluating orthodontic treatment programmed in C++ language and running on the Windows operating system.

TESTING & VALIDATION

The software is thoroughly tested in accordance with a documented test plan. This test plan is derived from the specifications and ensures that all controls and features are functioning properly. The software is validated together with end-users.

The performance testing remains unchanged from the company's own reference device submission, NemoCast K193003. The performance testing for the subject device is being leveraged from the company's own reference device including: design verification and validation testing.

Differences:

The Indications for Use statement between the subject and predicate devices are equivalent; minor differences in wording do not alter the intended use of the subject device. In addition, there are minimum differences in the software functions or technical requirements; none of these differences affect the safety and effectiveness of the subject device relative to the predicate, both can be considered equivalent.