January 18, 2024

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

Re: K232698
Trade/Device Name: NemoScan
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 1, 2023
Received: September 5, 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
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DHT8B: Division of Radiologic Imaging
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232698

Device Name

NemoScan

Indications for Use *(Describe)*

NemoScan is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in the field of application. The software reads imaging information output from medical scanners such as CBCT or CT scanners.

It is indicated for pre-operative simulation and evaluation of patient anatomy, dental implant placement, surgical instrument positioning, and surgical treatment options, in edentulous, partial edentulous or dentition situations, which may require a surgical guide. It is further indicated for the user to design such guides for, alone or in combination, the guiding of a surgical path along a trajectory or a profile, or to help evaluate a surgical preparation or step.

NemoScan software allows for surgical guide export to a validated manufacturing center or to the point of care.

Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable).
A surgical guide may require to be used with accessories.

NemoScan is intended to be used only for Adolescents (12-21 years of age) to adults (>21 years of age) patients.

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.

510(k) Summary

Premarket Notification Number K232698

Date of Summary: 01/16/2024

Substantial equivalence is claimed to the following devices:

Subject Device

Trade Name: NemoScan
Common Name: System, Image Processing, Radiological
Device Class: Class II
Product Code: QIH
Regulation Number: 21 CFR 892.2050
Classification Name: Medical image management and processing system

Predicate Device

Trade Name: coDiagnostiX Implant Planning Software (K130724)
Common Name: System, Image Processing, Radiological
Product Code: LLZ
Device Class: Class II
Regulation Number: 21 CFR 892.2050
Classification Name: Medical image management and processing system

Reference Device

Trade Name: NemoScan (K192571)
Common Name: System, Image Processing, Radiological
Device Class: Class II
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Classification Name: Medical image management and processing system

Name and Address of the Applicant/Sponsor

Software Nemotec S.L.
Av. Juan Caramuel,
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Indications for use

NemoScan is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in the field of application. The software reads imaging information output from medical scanners such as CBCT or CT scanners.

It is indicated for pre-operative simulation and evaluation of patient anatomy, dental implant placement, surgical instrument positioning, and surgical

treatment options, in edentulous, partial edentulous or dentition situations, which may require a surgical guide. It is further indicated for the user to design such guides for, alone or in combination, the guiding of a surgical path along a trajectory or a profile, or to help evaluate a surgical preparation or step.

NemoScan software allows for surgical guide export to a validated manufacturing center or to the point of care.

Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable).
A surgical guide may require to be used with accessories.

NemoScan is intended to be used only for Adolescents (12-21 years of age) to adults (>21 years of age) patients.

Device Description

NemoScan is a comprehensive diagnosis and treatment planning software for dental implantology intended to be used by dental professionals who have appropriate knowledge in surgical implantology and dental implants prosthesis. The software works with volume data sets imported from DICOM format produced by third-party CT/CBCT scanners and stored in a filedata repository. Additionally, optical scans of dental impressions can be imported from standard file formats like STL or PLY and registered over the volume to get reliable high definition of the anatomy of teeth and gums of the patients. The software is provided in three configurations: desktop, cloud and web.
Surgical planning is performed through convenient layouts of views, analysis of image data and the placement of virtual dental implants and optionally virtual prosthetic teeth. One patient file may contain multiple surgical plan proposals which allow the user to choose the ideal surgical plan.
Additional functions are available to the user for refinement of the surgical planning, such as:

- Import, organize, store images from CT or CBCT in DICOM format (optionally if the case has these images, called Volume Images).
- Import digital impressions of the teeth (scanned stone models and intraoral scanner) and/or implant files in STL or PLY format, and align them over the volume image (if exists).
- Import facial scanner or 3D photos in OBJ or PLY format.
- Measurements of distances and angles in 2D, for slices, and 3D, for 3D views.
- Merge the dental digital impressions into the CT/CBCT patient volume.
- Do Orientation of the Volume according to the Natural Head Position of the patient (Reorient the 3D volume).
- Patient gums, teeth, bones, mandibular nerves and sinus segmentation to help the planner in viewing those anatomical conditions in 3D and their corresponding cross sections in the 2D slices.
- Possibility of simulation of teeth extractions for immediate implants placement.
- Specific layouts of views with the selected implant centered to accurately positioning the virtual implant according to the anatomical volume conditions.
- Bone densitometry with a density statistic for density measuring in the area around a distance outside and inside the limits of the positioned

implant.
- Real time distances and angles to sensible areas like other implants, nerves, patient teeth, sinus, etc.
- Possibility of adding prosthetic teeth for designing the immediate loading prosthesis or just for helping in orienting the implants according to the prosthetic conditions.

NemoScan works with many manufacturers of implants, abutments, drills, analog, sleeves, hand pieces, etc., libraries to be used for simulation and treatment planning. The software allows importing these libraries and designing different kinds of surgical guides and immediate loading prosthesis to export the designed file in STL format. Finally, these designed files will be used to a validated manufacturing center or to the point of care.

The device has no patient contact nor does it control any life-sustaining devices.

Warning: Anatomical segmented structures cannot be used as sole information for the clinician to make clinical decisions.
3D manufacturing is out of NemoScan software control, depends on many external factors and lies within the sole responsibility of the user.

Warning: The guide must be fabricated based on the FDA cleared or legally marketed 3D printing fabrication method. The STL is to be exported to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable).

Substantial Equivalence Determination

The general intended use is identical for both the subject device and primary predicate device.
As to the indications for use, the subject device specifies the indicated patient conditions: for use in edentulous, partial edentulous, and dentition conditions. However, this is already included in the labeling of the primary predicate (K130724).
The purpose of this submission is also to expand the functionalities from desktop application to web application.

Similarities to Predicate

The subject and predicate devices are intended for supporting the pre-operative digital implant planning and design surgical guide files. They share the same fundamental principles of operation – Software is used to convert individual patient CT scans to digital models for subsequent implant planning.

The subject and predicate devices utilize image data obtained from a CT scan, which is input into validated commercially off-the-shelf (COTS) software applications to transfer patient imaging from DICOM to. STL format and manipulate the images to design a final guide file.

Both systems utilize implants, anatomical models, guides, pins, analog and abutments to design guide files. In addition, the systems design digital models and generate PDF case reports for the doctors to use for planning of implantology surgeries or to use during surgery.

The predicate device (K130724) and the subject device NemoScan includes Tooth-supported, Gingiva-supported and Bone-supported surgical guide design possibilities. Also, both systems have options to add a label to identify the surgical guide.

Differences to Predicate

The subject device differs from the predicate mainly in that the subject device is able to add prosthetic design data using the prosthesis wizard of the reference device. coDiagnostiX is able to connect to DWOS to access the wizard prosthesis.
coDiagnostiX uses DWOS Synergy interface to communicate with Dental Wings DWOS. It makes prosthetic design data available in coDiagnostiX and, in turn, sends planning. Also, DWOS Synergy interface would be used for mesh transformation.
The alternate workflow involving the printouts and manufacturing method using the manually operated gonyX is not included in the subject device.

Finally, the target population of the subject device is adolescents (12-21 years of age) to adults (>21 years of age), which is a subgroup of the general public of the predicate device.

Reference Devices

NemoScan (K192571) has been included as a reference device because it included all the immediate loading prosthesis features, mesh transformation, photo mapping and import 3D photograph.

Align 3D with Photos is the same functionality presented on the last NemoScan K192571 submission with the name Photo Mapping. Import 3D Photos (OBJ) is the same functionality presented on the last NemoScan K192571 submission with the name Import 3D Photograph. These functionalities have no medical purpose; they are used only for visualization.

Performance Testing

Although NemoScan (K192571) did not include exhaustive performance testing, the points Sterilization and Shelf Life, Biocompatibility, EMC and Electrical Safety are not applicable.
NemoScan (K192571) included Labeling and verification and validation testing Report.
The subject device NemoScan includes a performance testing report which justify the types of performance testing applicable to software as a medical device.

A risk assessment has been performed based on FDA guidance, “Use of RealWorld Evidence to Support Regulatory Decision-Making for Medical Devices, Aug 2017” with supporting peer-reviewed clinical literature to demonstrate the safety and effectiveness of the subject device for use of the new guides.

Non Clinical Performance Data

Process performance qualifications of the manufacturing process are conducted to assure a guide of a certain material can safely and effectively be manufactured. Worst case testing of representative guide designs is utilized. Expected results are met. This process performance qualifications includes centralized manufacturing and point of care procedures. The validated materials and manufacturing processes are safe and effective for their intended use.

Comparison of Technological Characteristics

The subject and predicate device are software based planning tools which allow for transfer of medical images, and design of 3D guides.

A comparison of the subject, reference device and predicate devices are provided in the table below.

A device comparison table of the subject, predicate, and reference devices is provided below:

Feature	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE
	NemoScan	coDiagnostiX, Implant Planning Software (K130724)	NemoScan, Software Nemotec S.L, (K192571)
Indications for Use Statement	NemoScan is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in the field of application. The software reads imaging information output from medical scanners such as CBCT or CT scanners. It is indicated for pre-operative simulation and evaluation of patient anatomy, dental implant placement, surgical instrument positioning, and surgical treatment options, in edentulous, partial edentulous or dentition situations, which may require a surgical guide. It is further indicated for the user to design such guides for, alone or in combination, the guiding of a surgical path along a trajectory or a profile, or to help evaluate a surgical preparation or step.	CoDiagnostiX is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in dental implantology and surgical dentistry. This software reads imaging information output from medical scanners such as CT or DVT scanners. It allows pre-operative simulation and evaluation of patient anatomy and dental implant placement. For automated manufacturing of drill guides in the dental laboratory environment, the coDiagnostiX can provide printouts of template plans for the creation of surgical templates using a manually operated gonyX table.	NemoScan is a software indicated for supporting the diagnostic and treatment planning of dental implants. NemoScan is software that is also used as an image segmentation system and for the transfer of imaging information from a scanner such as a CT scanner.

	NemoScan software allows for surgical guide export to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable). A surgical guide may require to be used with accessories.		
Classification	21 CFR 892.2050, Class II	21 CFR 892.2050, Class II	21 CFR 892.2050, Class II
Product Code	QIH	LLZ	LLZ
Product Code Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological
General Description	Dental Surgery Planning System	Dental Surgery Planning System	Dental Surgery Planning System
Prescription Use	Yes	Yes	Yes
Core Component	Stand-alone software	Stand-alone software	Stand-alone software
Target population	Adolescents (12-21 years of age) to adults (>21 years of age)	General public	Adults
Patient condition	For edentulous, partial edentulous or dentition situations	For edentulous, partial edentulous or dentition situations	non-specific
Input Source	CT / CBCT scanner	CT / CBCT, DVT scanners	CT / CBCT scanner
Input Data formats	DICOM, .stl, .ply, .obj files	DICOM, .stl files	DICOM, .stl, .obj files
Export	.stl file format	.stl file format	.stl file format

Printouts	Make reports of the implant treatment plan.	Make reports of the implant treatment plan.	Make reports of the implant treatment plan.
Anatomical site	Oral-maxillofacial regions	Oral-maxillofacial regions	Oral-maxillofacial regions
Physical output design per Planning	Yes	Yes	Yes
Minimum system requirements	PC with specified requirements on hardware, operating system and security (in user manual)	PC with specified requirements on hardware, operating system and security (in user manual)	PC with specified requirements on hardware, operating system and security (in user manual)
Image registration (alignment)	The scanned surface data acquired by the optical/intraoral scanner can be aligned to the CT/CBCT reconstruction through a point-based registration technique	The scanned surface data acquired by the optical/intraoral scanner can be aligned to the CT/CBCT reconstruction through a point-based registration technique	The scanned surface data acquired by the optical/intraoral scanner can be aligned to the CT/CBCT reconstruction through a point-based registration technique
Interface requirements	Desktop Application Web Application	Desktop Application	Desktop Application
DICOM Standard Compliant	Yes	Yes	Yes
Projects management	Project exporting/importing	Project exporting/importing	Project exporting/importing
Mean Features/ Tools	CAD tools to manipulate/modify/ render/import/export/sectioning patient models (teeth, upper/lower jaws), surgical item models, areas of interest. Includes: - Panoramic curve - Nerve detection - Virtual structures - Orient images to occlusal plane- Surgical item libraries - Bone density analyses, geometric measurements	CAD tools to manipulate/modify/ render/import/export/sectioning patient models (teeth, upper/lower jaws), surgical item models, areas of interest. Includes: - Panoramic curve - Nerve detection - Virtual structures - Orient images to occlusal plane- Surgical item libraries - Bone density analyses, geometric measurements	CAD tools to manipulate/modify/ render/import/export/sectioning patient models (teeth, upper/lower jaws), surgical item models, areas of interest. Includes: - Panoramic curve - Nerve detection - Virtual structures - Orient images to occlusal plane- Surgical item libraries - Bone density analyses, geometric measurements

Case visualization	2D gray value images 3D model rendering Panoramic mode MPR mode Individual editing of imaging artifacts 3D Photo in .Obj format Align 3D with Photos Image treatment	2D gray value images 3D model rendering Panoramic mode MPR mode Individual editing of imaging artifacts	2D gray value images 3D model rendering. Panoramic mode MPR mode 3D Photo in .Obj format Align 3D with Photos
Measurement tool	Distance/Angle Bone density measurement	Distance/Angle Bone density measurement	Distance/Angle Bone density measurement
Virtual Wax-up	Possible	Possible	Possible
Nerve tracing	Possible	Possible	Possible
Implant Preparation tools	Teeth segmentation and coordinate system; DICOM to STL conversion; Mesh transformation; Sinus segmentation; Reorient the 3D volume; Root and teeth segmentation; Teeth extractions; Panoramic curve;	Teeth segmentation and coordinate system; DICOM to STL conversion; Sinus segmentation; Reorient the 3D volume; Root and teeth segmentation; Teeth extractions; Panoramic curve;	Teeth segmentation and coordinate system; DICOM to STL conversion; Mesh transformation; Sinus segmentation; Reorient the 3D volume; Roots segmentation and complete teeth fusion; Teeth extractions; Panoramic curve;
Implant Planning tools	Implant, sleeve, drill, abutment, analog, and pin positioning; Custom Implant, Sleeve, Drill, Abutment, and Pin creation; Implant-to-implant, Implant-to-nerve canal, Sleeve-to-Sleeve, and Sleeve-to- STL surface distance/collision warning; Prosthesis wizards;	Implant, sleeve, drill, abutment, analog, and pin positioning; Custom Implant, Sleeve, Drill, Abutment, and Pin creation; Implant-to-implant, Implant-to-nerve canal, Sleeve-to-Sleeve surface distance/collision warning;	Implant, sleeve, drill, abutment, and pin positioning; Custom Implant, Sleeve, Drill, Abutment, and Pin creation; Implant-to-implant, Implant-to-nerve canal, Sleeve-to-Sleeve, and Sleeve-to-STL surface distance/collision warning

	Implant validations:		Prosthesis wizards; Implant validations;
Surgical guide design	Design the surgery guide based on the implant treatment plan, such as: ● Tooth-supported surgical guide design possible; ● Gingiva-supported surgical guide design possible; ● Bone-supported surgical guide design possible; ● Export of surgical guide design data set possible; ● Gingivectomy guide; ● Offset, thickness and connector setting possible; ● Add label text in surgical guide;	Design the surgery guide based on the implant treatment plan, such as: ● Tooth-supported surgical guide design possible; ● Gingiva-supported surgical guide design possible; ● Bone-supported surgical guide design possible; ● Gingivectomy guide; ● Export of surgical guide design data set possible; ● Offset, wall thickness and connector thickness setting possible. ● Add label text in surgical guide;	Design the surgery guide based on the implant treatment plan, such as: ● Tooth-supported surgical guide design possible; ● Gingiva-supported surgical guide design possible; ● Bone-supported surgical guide design possible; ● Offset, wall thickness and connector thickness setting possible; ● Export of surgical guide design data set possible;
Surgical protocol design and creation tool	Details protocol: available per implant providing detailed implant, sleeve and surgical protocol information together with images of the planning views; Surgical protocol: The sequence of surgical instruments to be used as specified by the selected guided surgery system (selected manufacturers only)	Details protocol: available per implant providing detailed implant, sleeve and surgical protocol information together with images of the planning views; Surgical protocol: The sequence of surgical instruments to be used as specified by the selected guided surgery system (selected manufacturers only)	Details protocol: available per implant providing detailed implant, sleeve and surgical protocol information together with images of the planning views; Surgical protocol: The sequence of surgical instruments to be used as specified by the selected guided surgery system (selected manufacturers only)
Other tools	Analog model, Virtual pour up and model builder.	N/A	N/A
Minimum system	OS - Windows 10 64-bit; 16 GB RAM Memory minimum	OS - Windows 7, 64-bit; 8GB RAM Memory minimum	Windows 7/8/8.1/10 4 GB RAM Memory minimum

hardware and software requirements	(CPU) - Intel Core i7 at 2.8GHz Network cards wired, minimum speed 1 Gb./sec; NVidia graphics card. Minimum 2 GB. VRAM HDD – 15 GB of free space	(CPU) - Intel® Core™ 2 Duo processor P8600 Graphics Card and Network cards- Not specified HDD – 128 GB of free space	16 GB RAM Memory recommended Intel Core i7 at 2.8GHz 5 GB free disc space or more Internet connection requirement
Payment model	Pay per use License Fee Annual Fee	License Fee Annual Fee	Pay per use License Fee Annual Fee

Conclusion from nonclinical and clinical tests

Image treatment includes functionalities such as: crop image, edit image and calibrate image. These functionalities are added to modify the input image or photo and it is not used for patients directly, these functionalities do not affect the security or effectiveness of the subject device.

Other tools from table before include: Analog model, Virtual pour up and model builder, which are functionalities used to export models to inspect them physically in 3D, but they are not used in the patient. These functionalities do not affect the security and effectiveness of the device.

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.