May 4, 2026

Cefla S.C.
% Ilenia Muccione
Regulatory Affairs Specialist
Via Selice Provinciale 23/A
Imola (Bo), BO 40026
ITALY

Re: K260716
Trade/Device Name: Neowise
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 5, 2026
Received: March 5, 2026

Dear Ilenia Muccione:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260716

Device Name
Neowise

Indications for Use *(Describe)*
Neowise is a medical imaging software intended for use in dental and medical applications as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to elaborate (retrieve, process, render, diagnose, review, and for non-medical application as store, print and distribute) images of both adults and pediatric patients.
Neowise is also software for simulating treatment options.
Neowise is also intended to be used for monitoring, recording, storing and displaying mandibular jaw position related to maxilla.
The software is for use by authorized healthcare professionals. Use of the software for surgical treatment planning requires that the user has the necessary medical training in maxillofacial surgery.

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.

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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510(k) SUMMARY, AS REQUIRED BY CFR 807.92 K260716

Submitter's Name:	CEFLA S.C.
Address:	Via Selice Provinciale 23/a Imola, BO 40026 ITALY Tel. +39 0542 653111 Fax +39 0542 653444
Establishment Registration Number:	3006610845
Summary Preparation Date:	March 05th,2026
Contact Person:	Ilenia Muccione, Regulatory Affairs
Telephone Number:	+39 0542 653459
Email:	regulatory@cefla.it

Trade/Device name:	Neowise
Classification Name:	Device: System, Image Processing, Radiological Medical image management and processing system Device Class: II Product Code: LLZ Regulation Number: 21 CFR §892.2050

Description:

Neowise is a medical imaging software intended for use in dental and medical applications as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to elaborate (retrieve, process, render, diagnose, review, and for non-medical application as store, print and distribute) images of both adults and pediatric patients.

Here reported below the key functionalities of Neowise software:

- acquisition
- visualization
- transfer
- processing
- analysis

of dental and cranio-maxillofacial image information.

Image-generating systems that can be used with the software include extraoral and intraoral devices and TWAIN compatible image sources.
Neowise can also forwarding images and additional data to external software (third-party software).

Neowise runs on a generic computer (Windows PC), which is considered a Workstation. All functionalities (acquisition, visualization, transfer, analysis and processing) are active and available when Neowise is installed on the Workstation.

Indication for Use:

Neowise is a medical imaging software intended for use in dental and medical applications as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to elaborate (retrieve, process, render, diagnose, review, and for non-medical application as store, print and distribute) images of both adults and pediatric patients.

Neowise is also software for simulating treatment options.
Neowise is also intended to be used for monitoring, recording, storing and displaying mandibular jaw position related to maxilla.
The software is for use by authorized healthcare professionals. Use of the software for surgical treatment planning requires that the user has the necessary medical training in maxillofacial surgery.

Identification of Predicate Device:

CEFLA S.C. will refer to the following predicate device:

Proprietary Name: Planmeca Romexis
Classification Name: System, Image Processing, Radiological, 21 CFR 892.2050
Product Code: LLZ
Applicant/Manufacturer: Planmeca Oy
Asentajankatu 6
Helsinki, 00880
FINLAND
510 (k): K200572

Identification of Reference Device:

CEFLA S.C. will refer to the following reference device:

Proprietary Name: DTX Studio Clinic
Classification Name: System, Image Processing, Radiological, 21 CFR 892.2050
Product Code: LLZ
Applicant/Manufacturer: Nobel Biocare AB
Nobel Biocare AB
Vastra Hamngatan 1
Göteborg, SE-411 17, Sweden
510 (k): K203156

Comparison of technological characteristics with the predicate and reference devices:

Characteristic	**Proposed Device**	**Predicate Device**	**Reference Device**
Device Name	**Neowise**	**Planmeca Romexis**	**DTX Studio Clinic**
Manufacturer	**CEFLA S.C**	**Planmeca Oy**	**Nobel Biocare AB**
510(K) No.	**-**	**K200572**	**K203156**
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Regulation Name	Picture archiving and communications system	Picture archiving and communications system	Picture archiving and communications system
Regulatory Class	Class II	Class II	Class II
Classification Product Code	LLZ	LLZ	LLZ
Indication for use	Neowise is a medical imaging software intended for use in dental and medical applications as a tool for	Planmeca Romexis is a medical imaging software intended for use in dental and medical care as tool	DTX Studio Clinic is a software program for the acquisition, management, transfer

		displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to elaborate (retrieve, process, render, diagnose, review, and for non medical application as store, print and distribute) images of both adults and pediatric patients. Neowise is also software for simulating treatment options. Neowise is also intended to be used for monitoring, recording, storing and displaying mandibular jaw position related to maxilla. The software is for use by authorized healthcare professionals. Use of the software for surgical treatment planning requires that the user has the necessary medical training in maxillofacial surgery.	for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, diagnose, review, store, print and distribute images of both adult and pediatric patients. Planmeca Romexis is also a preopartive software used for dental implant pallning. Based on the planned implant position a model of surgical guida gor a guided implant surgery can be designed. The designed bojects can be exported to manufacture a separate physical product. Planmeca Romexis is also intended to be sued for monitoring, recording, sotring and displaying mandibular jaw positions and movements relative to maxilla. Additionally, Planmeca Romexis includes monitoring features for Planmeca devices for maintenance process. The software is design to work as stand-alone or as an accessory to Planmeca imaging and Planmeca dental unit products in standard PC. The software is for use by authorized healthcare professionals. Use of the software for implant planning requires that the user has the necessary medical training	and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental restorative solutions. It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations

		in implantology and surgical dentistry. Use of the software for surgical treatment planning requires that the user has the necessary medical training in maxillofacial surgery. Indication of the dental implants do not change with guided surgery compared to conventional surgery.	
Main features			
Input data/Image acquisition	2D, 3D, optical impressions, 3D face photos, DICOM image data volumes	2D, 3D, optical impressions, 3D face photos	DICOM image data volumes, 2D and 3D images
Output data	Data is stored in local database. 2D and 3D image export and related reporting.	Data is stored in local database (also data can be shared by cloud management – refer to page 35 of Planmeca Romexis user manual) 2D and 3D image export and related reporting.	Data is stored locally or in remotely accessible database in the network (DTX Studio Core). 2D and 3D image export (DICOM image data volumes, 2D and 3D images such as (CB)CT scans and 2D images such as OPG/panorex images, acquisition of X-Ray images from intra-oral sensors, cephalometric images, intra-oral images and clinical pictures.), STL, PLY, NXA file export. Export implant or restorative treatment plan Diagnostic findings report export.
Image Processing methodology	Image processing, brightness & contrast, crop, annotations, measurements, import/export.	Image processing, brightness & contrast, crop, annotations,	Enhancement (image filter application), annotations, measurements (distance and

		measurements, import/export.	angular, volume and surface area for data segmentation), import/export. Airway volume segmentation. Alignment of surface scans, such as intra-oral or dental cast scans .STL/.PLY files with (CB)CT data for accurate implant planning
Software Feature: Patient Records			
List of exams associated with a selected patient	List of exams associated with a selected patient is reported on dedicated "Patient" tab section on Neowise user interface	The list of patients with dedicated list of exams for each patient is included on dedicated section "Patients" on the user interface.	The list of patients with dedicated list of exams for each patient is included on dedicated section "Patients" on the user interface.
Import exams	Data and related exam can be imported on the software including DICOM, Dental scans, Face scans,2D and 3D images	Data and related exam can be imported on the software including DICOM, Dental scans, Face scans,2D and 3D images	Data and related exams can be imported on the software including DICOM, Dental scans, Face scans,2D and 3D images
Software Feature: Scan data			
Scan Data (performing 2D examination)	It is possible to perform 2D scans (and related image capturing interfacing with proprietary devices).	It is possible to perform 2D scans (and related image capturing interfacing with proprietary devices)	It is possible to perform 2D scans (and related image capturing interfacing with proprietary devices)
Scan Data (performing 3D examination)	It is possible to perform 3D scans	It is possible to perform 3D scans	It is possible to perform 3D scans
Software Feature: Image management			
Change image palette	A cursor within the window enables the modification of the image brightness and contrast: dragging the cursor to the right/left changes the contrast and to the top/bottom the brightness.	The software allows to adjust contrast, brightness and softness	Information not available

	Measurement tools	Measurement button allows the user to draw a segment on the image to make a measurement. Continuous measurement tool button allows the user to draw several contiguous segments on the image to make a measurement.	It is possible to perform a measurement of a length (length -single which is the segment and polyline which is the continuous measurement tool)	The software allows measurement tools
	Software Feature: Twain and third-party			
	Twain sources (data import)	It is possible to select and acquire images from external TWAIN devices.	It is possible to perform scanning from TWAIN sources	It is possible to perform scanning from TWAIN sources
	Bench testing			
	Software validation	IEC62304 + Guidance FDA on MD SW Risk management following the ISO 14971	IEC62304 + Guidance FDA on MD SW Risk management following the ISO 14971	IEC62304 + Guidance FDA on MD SW Risk management following the ISO 14971
Non-clinical Performance Testing:	Neowise 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 standard. Design Control Activities, including risk management following the ISO 14971 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. V&V testing evidences as per "Content of Premarket Submissions for Device Software Functions " issued on June 14, 2023, is also included as part of this submission.			
Clinical Testing:	Clinical performance testing was not conducted.			
Conclusion:	CEFLA S.C. considers Neowise to be substantially equivalent to the predicate device. This conclusion is based on the similarities in intended use, principle of operation, functional design, and established medical use. Differences between the devices shown in the comparison section above are minor and do not have any negative effect on substantial equivalence.			