March 6, 2026

Nano4imaging GmbH
Natalie Theisen
Director Regulatory Affairs and Quality Management
Life Science Centre
Merowingerplatz 1
Duesseldorf, NRW 40225
Germany

Re: K253262
Trade/Device Name: EmeryGlide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 29, 2025
Received: September 29, 2025

Dear Natalie Theisen:

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 Medical Device File (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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2026.03.06 23:28:07 -05'00'

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253262

Device Name
EmeryGlide

Indications for Use *(Describe)*
EmeryGlide is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures.

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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1. Special 510(k) Summary

1.1. Submitters Information (807.92(a)(1))

	Owner/Operator
Prepared for:	Nano4Imaging GmbH Life Science Center Merowingerplatz 1 40225 Düsseldorf, Germany + 49 211 542 41712
Contact details:	Natalie Theisen Director Regulatory Affairs and Quality Management Phone: +49 (0) 241 56528261 / +49 (0) 15165477405 Email: nat@nano4imaging.com
Prepared by:	Sjef Cremers, *Ph.D.* Senior Special Project Manager
Date of preparation:	09/29/2025

1.2. Device Name (807.92(a)(2))

Device Trade Name:	EmeryGlide™
Device Common Name:	Guide Wire
Classification Name:	Wire, Guide, Catheter
Classification Pannel:	Cardiovascular
Regulation:	21 CFR 870.1330
Product Code:	DQX
Classification:	Class II

1.3. Predicate Device (807.92(a)(3))

The legally marketed device to which substantial equivalency is claimed is:

Predicate device	Manufacturer	510(k)	Date
MRWire Guide Wire	Contract Medical GmbH for Nano4Imaging GmbH	K173423	11/17/2017

1.4. Reason for Special 510(k) Submission

The purpose of this Special 510(k) submission is to establish substantial equivalence of EmeryGlide™ to the predicate MRWire Guide Wire (K173423). The subject device incorporates minor technical modifications, including the use of an alternative PTFE colorant, a change in pouch material, transfer to a new FDA-registered contract sterilizer and manufacturer, and an extension of shelf life. These modifications do not alter the device's intended use or fundamental scientific technology, and verification/validation activities confirmed that the EmeryGlide™ is substantially equivalent to the predicate device.

1.5. Device Description

Principle of Operation Technology

EmeryGlide™ is operated by manual process.

Design/Construction

EmeryGlide™ is a sterile, disposable guidewire for the introduction and/or placement of diagnostic or interventional devices. EmeryGlide™ is constructed from a high strength core composite of glass fibers and polymers, protected by a high-strength aramid fiber mantle and covered with a PTFE extrusion. The distal tip of EmeryGlide™ is marked with discrete ring markers for MRI and X-Ray visibility and comes in an angled configuration. EmeryGlide™ is supplied sterile and non-pyrogenic. EmeryGlide™'s diameter is 0.035" (0.89 mm).

MRI Safety Information

Non-clinical testing has demonstrated that EMERYGLIDE™ is MR Conditional.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3.0 T
- Maximum spatial field gradient of 3600 Gauss/cm (36.0 T/m) for 1.5 Tsystems
- Maximum spatial field gradient of 1800 Gauss/cm (18.0 T/m) for 3.0 Tsystems
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Operating Mode at 1.5 T)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Operating Mode at 3.0 T)

Under the scan conditions defined above, EmeryGlide expected to produce a maximum temperature rise of less than 0.6 °C after 15 minutes continuousscanning.

In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from EmeryGlide™ when imaged with a gradient echo pulse sequence and a 3 T MRI system.

Specifications

The specifications for EmeryGlide™ are provided in the table below.

Table 1.1: EmeryGlide™ Specifications

Part	Specification
Model Number	EG18008901
Diameter of Guide Wire	0.035”
Length of Guide Wire	180 cm
Distal tip shape processing	Preshaped
Tip Configuration	Angled
Tip length	40 mm
Outer sleeve material	PTFE
MRI and X-ray visibility	Passive markers at discrete positions 0, 2, 4 cm from the tip
MRI Labeling	MR Conditional
Shelf life	1 year

1.6. Indications For Use (807.92(a)(5))

EmeryGlide™ is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures.

Contraindications:

EmeryGlide™ is not intended for coronary or cerebral vasculature.

1.7. Substantial Equivalence Comparison (807.92(a)(6))

EmeryGlide™ subject of this special 510(k) is substantially equivalent in intended/indications for use, technology /principle of operation, and performance to the MRWire Guide Wire manufactured by Nano4Imaging GmbH.

A comparison of the technological characteristics is summarized in the table below.

Table 1: Summary of Comparative Information

Characteristics	Subject Device EmeryGlide™ EG18008901	Predicate MRWire CV18035S and CV18035A
510(k) number	K253262.	K173423
Trade name	EMERYGLIDE™	MRWire Guide Wire
Models	EG18008901	CV18035S (FG-02175-006) and CV18035A (FG-02175-007)
Indications for use	EmeryGlide™ is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures.	The MRWire Guide Wire is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures.
Principle of operation	Manual operation	Manual operation

Diameter	0.035” (0.89 mm)	0.035” (0.89 mm)
Effective lengths	180 cm	180 cm
Distal shape configuration	Angled	Angled, Straight
Sterilization method / Sterilization Assurance Level (SAL)	Ethylene oxide, SAL 10^{-6}.	Ethylene oxide, SAL 10^{-6}.
Shelf Life	1 year	6 months
MRI compatibility	Yes	Yes
MRI visibility	Discrete markers	Discrete markers
X-ray visibility	Yes	Yes
Material	Glass fibers, aramid fibers and PTFE	Glass fibers, aramid fibers and PTFE
Outer sleeve material	Blue PTFE Heat Shrink Tubing	Blue PTFE Heat Shrink Tubing
Coating	No	No
Package Material	Pouch: Coated 1073B Tyvek® / 100ga BON, 15” x 15” Packer: Carton, 15” x 15” x 0.5” Shipper: Carton, 15” x 15” x 3.25”	Pouch: Flat PET-O/PP 12/40 Paper, 500 mm x 380 mm Packer: Carton, 380 x 380 x 10 mm Shipper: Carton, 390 x 390 x 80 mm

1.8. Non Clinical Tests (807.92(b)(1))

Performance

Performance testing was conducted to evaluate the mechanical and functional characteristics of the EmeryGlide™ throughout its labeled shelf life, verify conformity to applicable ISO/ASTM standards, and demonstrate substantial equivalence to the predicate device (K173423). With the exception of biocompatibility, bioburden, and bacterial endotoxin (LAL) testing, all performance tests were performed on both non-aged and accelerated-aged samples to simulate a 1-year shelf life. All samples tested met the applicable acceptance criteria, and substantial equivalence was established.

Table 2*:* Performance Testing per ISO Standard/ASTM

Test Item	Reference Standard
Flexing and Bending Resistance	ISO 11070:2014, Section 8.5
Bending Modulus	ISO 14125:2011
Packaging Seal Strength	ASTM F88/F88M-23
Packaging Integrity – Dye Penetration	ASTM F1929-23 Red
Packaging Integrity – Visual Inspection	ASTM F1886/F1886M-16(2024)
Packaging Integrity – Bubble Leak Test	ASTM F2096-11 (R2019)
Transportation Simulation	ISTA 3A:2018
Bioburden Testing	ISO 11737-1:2018
Biocompatibility – Cytotoxicity	ISO 10993-5:2009
Biocompatibility – Sample preparation and reference material	ISO 10993-12:2021/Amd 1:2025
Biocompatibility – Toxicological risk assessment	ISO 10993-17:2023
Biocompatibility – Chemical characterization	ISO 10993-18:2020
LAL/Endotoxin Testing	USP <85> / AAMI ST72:2019
Sterilization Adoption	ISO 11135:2014 + Amd.1:2019 TIR28:2016/(R)2020
Particulate evaluation	USP <788>, AAMI TIR42:2021

Additionally, performance testing other than that recommended in the above ISO standard was performed on the device in accordance with FDA guidance documents and/or in-house standards. The subject device complies with the acceptance criteria established based on the predicate device and/or the FDA guidance documents, as shown in the table below.

Table 3: Performance Testing per In-house Standard

Test Item	Reference
U-Turn Test (worst-case anatomical kink resistance)	In-house protocol, FDA-reviewed
Simulated Use Test (vascular phantom model)	In-house protocol
Product dimension	In-house standard

Performance testing demonstrated that EmeryGlide™ conformed to the recognized consensus ISO standards, FDA guidance documents or in-house standards, is substantially equivalent to the predicate device.

Biocompatibility

In accordance with ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, EmeryGlide™ is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours). This is the same classification as the predicate MRWire Guide Wire (K173423) intended for vascular use.

All new blood-contacting materials of the subject device were evaluated through biocompatibility testing in accordance with FDA Guidance “Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process” (September 8, 2023) and the FDA-recognized ISO 10993-1 standard.

Sterilization

The device was adopted into an existing sterilization cycle that was validated in accordance with ISO 11135:2014 + Amd.1:201, Sterilization of health-care products - Ethylene Oxide -

Requirements for development, validation and routine control of a sterilization process for medical devices, to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Pyrogenicity evaluation confirmed that the device is non-pyrogenic, with no bacterial endotoxin contamination (USP <85>, ANSI/AAMI ST72:2019) and no evidence of material-mediated pyrogenicity.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971: 2019, Medical devices- Application of risk management to medical devices, and no new risks were identified.

1.9. Clinical Tests (807.92(b)(2))

This 510(k) does not include data from clinical tests.

1.10. Conclusion (807.92(b)(3))

In summary, EmeryGlide™, subject of this special 510(k), is substantially equivalent in its intended use/indications for use, technology/principal of operation, and performance to the predicate device MRWire Guide Wire cleared under k173423.