November 17, 2017

Nano4Imaging GmbH
% Ms. Judith Harrington
Consultant
G&L Scientific
9 Highland Ave
Derry, New Hampshire 03038

Re: K173423
Trade/Device Name: MRWire Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 4, 2017
Received: November 1, 2017

Dear Ms. Harrington:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
MRWire Guide Wire

Device Name
K173423

Indications for Use *(Describe)*
The MRWire Guide Wire 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))

Prepared for: **Owner/Operator**

Nano4Imaging GmbH
Zentrum Für Biomedizintechnik
Pauwelsstrasse 17
52074 Aachen, Germany
+49 241 5656 28 261

Contact details:

Christoph R. Manegold (CEO)

Phone: +49 (0) 241 56528261 / +49 (0) 171 770 4392

Email: cm@nano4imaging.com

Prepared by:

Sjef Cremers, *Ph.D.*

Senior Scientist

Date of preparation:

11/14/2017

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

Device Trade Name:	MRWire Guide Wire
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	Nano4Imaging GmbH	K160594	11/22/2016

1.4. Reason for Special 510(k) Submission

The purpose of this special 510(k) submission is establishing substantial equivalency to a legally marketed device as a result of a technical modification in the new design. The technological differences between the predicate cleared under K160594 and the subject device are listed in the table below. Based on the Risk Analysis, the following Design Control Activities were identified.

Modification	Differences in technological characteristics	Benchmark Test	Difference/comments Predicate Device
1	PTFE heat shrink tube instead of Pebax® outer extrusion at the outside	• Simulated Use Test	No differences in the Simulated Use Test.
		• Flexing and Bending Resistance	No differences in Flexing and Bending Resistance Test.
		• Biocompatibility Testing	Under the applied conditions the device is from biological risks.
		• Torquability Test	The torqueability of the subject device is slightly increased compared to the predicate.
		• Particulate Testing	Both generate no particles.
		• U-Turn Test	No differences in the U-turn test.
		• Usability Scoring Test	No difference in usability.
2	The glass fiber core diameter has decreased from 0.52 mm to 0.50 mm mm to make the surface suitable for PTFE extrusion	• Simulated Use Test	No differences in the Simulated use Test.
		• Fracture Test	No differences in the Fracture Test.
		• Tensile Strength Test	The tensile strength is slightly higher than the predicate device, making it better to withstand normal tensile loading for the intended use.
		• Bending Module Test (shaft)	Shaft stiffness is in the same order of magnitude.
		• Torquability Test	The torqueability of the subject device is slightly increased compared to the predicate.
		• Torque Strength Test	The torque Strength of the subject device is increased compared to the predicate making it better to withstand normal rotational loading for the Intended use.
		• U-Turn Test	No differences in the U-turn test.
		• Usability Scoring Test	No difference in usability.
3	Tip is preformed instead of grinding, no need for Pebax® tip extrusions	• Simulated Use Test	No differences in the Simulated use Test.
		• Tensile Strength Test	The tensile strength is slightly higher than the predicate device, making it better to withstand normal tensile loading for the intended use.

Modification	Differences in technological characteristics	Benchmark Test	Difference/comments Predicate Device
		• Radiopacity Testing	Both have radiopaque elements in the tip.
		• Torquability Test	The torqueability of the subject device is slightly increased compared to the predicate.
		• Tip Flexibilityy Test	The tip flexibility of the subject devices is comparable to the predicate.
		• Torque Strength Test	The torque Strength of the subject device is increased compared to the predicate making it better to withstand normal rotational loading for the Intended use.
		• Usability Scoring Test	No difference in usability.
		• MRI Compatibility	No difference in MRI labelling.

1.5. Device Description

Principle of Operation Technology

The MRWire Guide Wire is operated by manual process.

Design/Construction

The MRWire Guide Wire is a sterile, disposable guide wire for the introduction and/or placement of diagnostic or interventional devices. The MRWire 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 the MRWire is marked with discrete ring markers for MRI and X-Ray visibility and comes in different configurations such as straight and angled. Guide wires are supplied sterile and non-pyrogenic. The MRWire's diameter is 0.035" (0.89 mm).

MRI Safety Information

Non-clinical testing has demonstrated the MRWire Guide Wire is MRConditional.

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 absorptionrate (SAR) of 4.0 W/kg (First Level Operating Mode at 1.5T)
- Maximum MR system reported, whole body averaged specific absorptionrate (SAR) of 4.0 W/kg (First Level Operating Mode at 3.0T)

Under the scan conditions defined above, MRWire Guide Wire is expected to produce a maximum temperature rise of less than 0.6 °C after 15 minutes continuous scanning.

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

Specifications

The specifications for MRWire Guide Wire are provided in the table below.

Table 1.1: MRWire Guide Wire Specifications

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

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

The MRWire Guide Wire is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures.

Contraindications:

The MRWire Guide Wire is not intended for coronary or cerebral vasculature.

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

The MRWire Guide Wire, 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 on the table below.

Nano4Imaging

Table 1.2 Summary of Comparative Information

Characteristics	Subject Device MRWire Guide Wire CV-G-18035S and CV-G-18035A	Predicate MRWire CV18035S and CV18035A
510(k) number	K173423	K160594
Trade name	MRWire Guide Wire	MRWire Guide Wire
Models	CV-G-18035S (FG-02175-006A) and CV-G-18035A (FG-02175-007A)	CV18035S (FG-02175-006) and CV18035A (FG-02175-007)
Indications for use	The MRWire Guide Wire 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”	0.035”
Effective lengths	180 cm	180
Distal shape configuration	Angled, straight	Angled, straight
Sterilization method / Sterilization Assurance Level (SAL)	Ethylene oxide (cycle CMI 01 EQ). SAL 10^{-6}.	Ethylene oxide (cycle CMI 01 EQ). SAL 10^{-6}.
Shelf Life	6 months	6 months
MRI compatibility	Yes	Yes
MRI visibility	Discrete markers	Discrete markers
X-ray visibility	Yes	Yes

Characteristics	Subject Device MRWire Guide Wire CV-G-18035S and CV-G-18035A	Predicate MRWire CV18035S and CV18035A
Material	Glass fibers, aramid fibers and PTFE	Glass fibers, aramid fibers and Pebax
Coating	No	No

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

Performance

Performance testing was conducted to evaluate the performance of the MRWire Guide Wire throughout the labeled shelf life, verify conformity to applicable standards and demonstrate substantial equivalence to the predicate devices. With the exception of the Radiopacity test, biocompatibility and the sterilization validation the following performance tests were performed on non-aged and accelerated-aged MRWire Guide Wire Samples. However, the particulate test and the Usability test were performed only on accelerated aged samples. All samples tested met the applicable acceptance criteria, and no new issues of safety and effectiveness were raised by the testing performed.

Table 1.3: Performance Testing per ISO Standard/ASTM

Test Item	Reference
Surface	Sec. 4.3 of ISO 11070: 2014
Radiodetectability	Sec. 4.5 of ISO 11070: 2014, ASTM F640-12
Fracture Test	Sec. 8.4 of ISO 11070: 2014
Flexing Test	Sec. 8.5 of ISO 11070: 2014
Peak Tensile Force of guidewire	Sec. 8.6 of ISO 11070: 2014
Bending Module	EN ISO 14125:2011

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 5.4: Performance Testing per FDA Guidance Documents and/or In-house Standard

Test Item	Reference
Peak Tensile Force of guidewire	3.a of FDA Guidance[a] In-house Standard
Torque strength	3.b of FDA Guidance[a] In-house Standard
Torqueability	3.c of FDA Guidance[a] In-house Standard
Tip flexibility	3.d of Guidance[a] In-house Standard
Catheter compatibilty	3.e of FDA Guidance[a] In-house Standard
Particulate evaluation	USP <788>, AAMI TIR42 (2010)
MRI Compatibility	FDA Guidance[b]
Product dimension	In-house Standard
U-Turn Test	In-house Standard
Simulated Use Test	In-house Standard
Usability Scoring Test	In-house Standard

a) *Coronary and Cerebrovascular Guidewire Guidance, January 1995*
b) *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, issued December 11, 2014*

Performance testing demonstrated that the MRWire Guide Wire conformed to the recognized consensus ISO standards, FDA guidance documents or in-house standards, is substantially equivalent to the predicate device for its shelf life.

Biocompatibility

In accordance with ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, the MRWire Guide Wire is classified as an Externally Communicating Devices, Circulating blood, Limited Contact (<24 hrs). This is the same classification as the predicate MRWire Guide Wire (K160594) which is intended for vascular use.

All the new blood contacting materials from the subject device were evaluated by extended biocompatibility testing in accordance with FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. Per ISO 10993-1 showed that under the applied conditions, the device is free from biological hazards.

Sterilization

The device was adopted into an existing sterilization cycle that was validated in accordance with ISO 11135: 2014, 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 $10^{-6.}$

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971: 2007, 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, MRWire Guide Wire, 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 k160594. There are no significant differences that raise any new issues of safety and effectiveness.