DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 22, 2016

Nano4Imaging GmbH
Mr. Christoph R. Manegold
CEO
Pauwelsstrasse 17
52074 Aachen Germany

Re: K160594
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 12, 2016
Received: October 17, 2016

Dear Mr. Manegold:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Brian D. Pullin -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)*
K160594

Device Name
MRWire Guide Wire

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

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

A. Submitters, name/contact details

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Prepared By: Sjef Cremers, *Ph.D.*
Senior Scientist
Date of preparation: 11/15/2016

B. Device Name

Device Common Name: Guide Wire
Device Trade Name: MRWire Guide Wire
Classification Name: Wire, Guide, Catheter

C. Predicate device

Predicate device	Manufacturer	510(k)	Date
Radifocus® Guidewire M	Terumo Corporation	K863138	11/20/1986

D. Classification

Class II
21 CFR § 870.1330,
Product code: DQX
Division of Cardiovascular Devices

E. Device Description

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. The distal tip of the MRWire is marked with discrete ring markers for MRI visibility and comes in different configurations such as straight and angled. Additionally, the Pebax® tip extrusion, contains $BaSO_4$ for X-Ray visibility.
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 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 T systems
- Maximum spatial field gradient of 1800 Gauss/cm (18.0 T/m) for 3.0 T systems
- 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, 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.

F. Intended 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.

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

G. Design/Materials

Differences MRWire Guide wire and the predicate device - Radifocus Guidewire M cleared under K863138 relates to the materials used.

H. Comparison of Technological Characteristics

Part	**MRWire**	**Radifocus Guide Wire M cleared under K863138**
Principle of operation	Manual operation	Manual operation
Diameter	0.035”	0.018" - 0.038"
Effective lengths	180 cm	150 - 300 cm
Shape of wires	Angled, straight	Angled, straight, J shaped
MRI compatibility	Conditional	No
MRI visibility	Discrete marker(s)	No
X-ray visibility	Yes only tip	Yes continuous

I. Performance

The following verification tests were performed to demonstrate the substantial equivalence of MRWire Guide Wire to **Radifocus Guidewire M**

- Proximal shaft stiffness
- Bend strength
- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Catheter Compatibility
- Dimensional Verification

- Biocompatibility
- MR Compatibility
- Packaging Testing
- Shelf life Testing
- Sterilization Testing

This testing has confirmed that the performance of MRWire Guide Wire is substantially equivalent to the performance of the predicate device the Radifocus Guidewire M which was cleared under K863138.

J. Preclinical information

Preclinical studies were performed at the Department of Cardiology (Johns Hopkins Division of Medicine) in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), and has shown that both straight and angled tip MRWire Guide Wires can be inserted and maneuvered to different target sites (*e.g.* aortic arch, vena cava) with no difficulties. Testing was also conducted in the common carotid but some difficulties were noted in this vasculature due to the pig anatomy. MR imaging in swine was optimal and the MR Wire was well visible in all target sites without causing changes in vital parameters.

K. Clinical information

Clinical studies were performed at the German Heart Centre in Munich (Germany) in compliance with European regulations (MEDDEV 2.12-2.) as part of the ongoing Post-Market Clinical Follow-up study in patients with congenital heart disease. The obtained results shows that the wires can be safely and effectively maneuvered in the MRI suite to reach the intended target sites such as right atrium, right ventricle, pulmonary artery and the aortic arch in interplay with catheters of ≥ 5F.

L. Conclusion

The MRWire Guide Wire is substantially equivalent in intended use, design, technology/principles of operations, and performance to the predicate device the Radifocus Guidewire M, cleared under K863138.