DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 18, 2017

NORAS MRI products GmbH
% Zahed Sedighiani
Msc. Medical Engineering
Leibnizstr. 4
Hoechberg, Bavaria D-97204
GERMANY

Re: K162651
Trade/Device Name: Breast BI 7 MR Coil Mammavention 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: December 27, 2016
Received: January 5, 2017

Dear Zahed Sedighiani:

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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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 on last page.

510(k) Number *(if known)*
K162651

Device Name
Breast BI 7 MR Coil Mammavention 3T

Indications for Use *(Describe)*
The intended use of Breast BI 7 MR Coil 3T Mammavention is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the female breast. It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal ad oblique images of the internal structures of the female breast. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.
The included Breast Biopsy Unit permits MR guided breast biopsy and wire localization of lesions can be performed by a trained physician.

The coil system Breast BI 7 MR Coil Mammavention 3T can be used with the following MRI systems:

3T: Siemens 3T: Skyra, Skyra fit, Prisma, Prisma fit, Spectra

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

510(k) Summary

Breast BI 7 MR Coil 3T Mammavention

Date of Summary Preparation: November 03, 2016

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

1. General Information

Importer/Distributor
Name and Address
NORAS MRI products GmbH
Leibnizstr.4
97204 Hoechberg / Germany

ERN: 3004929307
Owner/Operator Number: 9071737

Manufacturing Site
Name and Address
NORAS MRI products GmbH
Leibnizstr.4
97204 Hoechberg / Germany

ERN: 3004929307
Owner/Operator Number: 9071737

2. Contact Person

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3. Device Name and Classification

Trade Name:	Breast BI 7 MR Coil 3T Mammavention
Common Name:	Breast BI 7 MR Coil 3T Mammavention
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Panel:	Radiology
CFR Number:	21 CFR § 892.1000
Device Class:	II
Product Code:	90MOS

4. Device Description

The Breast BI 7 MR Coil 3T Mammavention described in this document has been designed, depending upon model type, for use with a SIEMENS MRI system with field strength of 3 T. The coil system serves solely as a receiving coil for the reception of high frequency signals from the hydrogen -(^{1}-H) nuclei. The hydrogen nuclei are induced into precession by the transmitting coil of the MRT device. The processing magnetization induces potential differences in the Breast BI 7 MR Coil 3T Mammavention which are digitized and further processed in the MRT system

5. Intended Use / Indications for Use

The intended use of **Breast BI 7 MR Coil 3T Mammavention** is, in conjunction with a Magnetic Resonance Scanner, the MR examination of the female breast. It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal ad oblique images of the internal structures of the female breast. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.
The included Breast Biopsy Unit permits MR guided breast biopsy and wire localization of lesions can be performed by a trained physician.

The coil system **Breast BI 7 MR Coil Mammavention** can be used with the following MRI systems:

3T: Siemens 3T: Skyra, Skyra fit, Prisma, Prisma fit, Spectra

6. Substantial Equivalence

NORAS MRI product GmbH believes that, within the meaning of the Safe Medical Devices Act of 1990, the Breast BI 7 MR Coil 3T Mammavention is substantially equivalent to the following multipurpose coil:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Product Code	Comparable Properties
Breast Biopsy 4-Ch Coil MR-BI320-PA 3T	K082373	Aug 29, 2008	90MOS	Proton imaging High resolution of breast anatomic regions

7. Summary of Technological Characteristics of the Principal Device as Compared with the predicate Device

Summary of technological characteristics of the **Breast BI 7 MR Coil 3T Mammavention** are the same as for the predicate device **Breast Biopsy 4-Ch Coil MR-BI320-PA 3T**

8. General Safety and Effectiveness Concerns

The **Breast BI 7 MR Coil 3T Mammavention** is conform with the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the IEC standards for safety issues with the Magnetic Resonance Imaging Devices, IEC 60601-2-33:2002. All device testing have been completed successfully before device clearance. This assures that the performance of this device can be considered safe and effective when used with the currently available Siemens MAGNETOM 3T The power tests which have been done by MRI manufacturer for the whole system can be found in 017_20160728_Prisma_Third_Party_Power_Test_Breast_BI_7.

9. Conclusion as to Substantial Equivalence

NORAS MRI products GmbH believes that, within the definition of the Safe Medical Devices Act of 1990, the **Breast BI 7 MR Coil 3T Mammavention** is substantially equivalent to the predicate device listed above.

Zahed Sedighiani
QM & RA Manager

December 27, 2016