



February 16, 2018

Noras MRI products GmbH
Jens Heidenmann
Official Correspondent
Leibnizstrasse 4
Hoechberg, 97204 De

Re: K180123

Trade/Device Name: Breast BI 7 MR Coil 1.5T Mammavention
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: December 28, 2017
Received: January 16, 2018

Dear Jens Heidenmann:

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,

 For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K 180123

Device Name

Breast BI 7 MR Coil Mammavention 1.5T (PN:118879)

Indications for Use (Describe)

The intended use of Breast BI 7 MR Coil 1.5T 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 and 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 1.5T can be used with the following MRI systems:

1.5T: Siemens 1.5T: Avanto fit, Aera, Amira

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



510(k) Summary

Breast BI 7 MR Coil 1.5T Mammavention

Date of Summary Preparation: 2018 – 02 - 14

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 1.5T Mammavention (PN:118879)
Common Name: Breast BI 7 MR Coil 1.5T Mammavention
Classification Name: Magnetic Resonance Diagnostic Device
Classification Panel: Radiology
CFR Number: 21 CFR § 892.1000
Device Class: II
Product Code: 90MOS
Submission Number: K180123

4. Device Description

The Breast BI 7 MR Coil 1.5T 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 1.5T 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 1.5T 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 and 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 1.5T Mammavention** can be used with the following MRI systems:

1.5T: Siemens 1.5T: Avanto fit, Aera, Amira

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 1.5T Mammavention is substantially equivalent to the following multipurpose coil:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Product Code	Comparable Properties
Breast BI 7 MR Coil 3T Mammavention	K162651	January 18 2017	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 1.5T Mammavention** are the same as for the predicate device **Breast BI 7 MR Coil 3T Mammavention**

8. General Safety and Effectiveness Concerns

The **Breast BI 7 MR Coil 1.5T 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 60601-2-33:2011. 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 1.5T The power tests which have been done by MRI manufacturer for the whole system can be found in 076_Third_Party_Power_Test_Breast_BI_7_MR_Coil_1.5T.pdf.

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 1.5T Mammavention** is substantially equivalent to the predicate device listed above.



Jens Heidenmann
QM & RA Manager

February 14, 2018