NORAS MRI Products GmbH
% Daniel Kamm
Principal Engineer
Kamm & Assosciates
8870 Ravello Ct
NAPLES FL 34114

April 8, 2022

Re: K220144
Trade/Device Name: Breast BI Coil Set 0.55T; Breast BI 7 MR Coil Set 1.5T; Breast BI 7 MR Coil Set 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: February 17, 2022
Received: February 18, 2022

Dear Daniel Kamm:

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. 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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K220144

Device Name
Breast BI Coil Set 0.55T; Breast BI 7 MR Coil Set 1.5T; Breast BI 7 MR Coil Set 3T

Indications for Use *(Describe)*

The intended use of the Breast Coil 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 placement of localization-wire by a trained physician. For use with Siemens 0.55T, 1.5T, and 3T systems

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.

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**510(k) Summary K220144**

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Date Prepared: April 8, 2022

A) SUBMITTED BY: NORAS MRI Products GmbH, Inc

B) CONTACT: Manuel Noras, Chief Executive Officer

C) Device Identification

Trade/Device Names: Breast BI Coil Set 0.55T; Breast BI 7 MR Coil Set 1.5T; Breast BI 7 MR Coil Set 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS

D) Predicate Device: K162651

Manufacturer: NORAS MRI Products GmbH
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

Additional Predicate Device: K180123

Manufacturer: NORAS MRI Products GmbH
Trade/Device Name: Breast Bl 7 MR Coil 1.5T Mammavention
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS

D) DEVICE DESCRIPTION: These three models are known as specialty MRI coils for use in generating MRI images of the female breast. MRI procedures that include the evaluated device are conducted for clinical purposes at the discretion of the ordering physician.
The Breast BI Coil Sets described in this document has been designed, depending upon model type, for use with an MRI system with field strength of 0.55T 1.5T or 3.0T.

The coil system consists of pure receiving coils 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 MRI device.

The precise magnetization induces potential differences in the Breast BI Coil Sets which are digitized and further processed in the MRI system.

The Breast BI Coil Sets consist of a rigid Coil Frame with Immobilization, Biopsy and Breast Coil System. Imaging is performed with a 7-Channel ”phased array“ Coil developed and manufactured by the NORAS company. The coils are mounted in the rigid Coil Frame. Interconnection is handled by the software of the MRI.

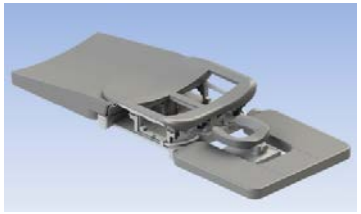
The Breast BI Coil Set 0.55T is an innovative concept designed to offer flexible use to meet the needs of the procedure to be performed in your clinic. It is removable and enables the biopsy device to be used with the respective corresponding coil with the different field strengths. The rigid Coil Frame forms a high resolution, 7-channel “phased array” configuration.

The Coil Frame is made of fiberglass-reinforced polycarbonate. The surface has been finished with Alexit biocompatible coating. The breast cushion and the headrest are made of PE

E) INDICATIONS FOR USE The intended use of the Breast Coil 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 placement of localization-wire by a trained physician. For use with Siemens 0.55T, 1.5T, and 3T systems.

F) SUBSTANTIAL EQUIVALENCE COMPARISON AND DISCUSSION: Except for the new MR field strength of 0.55 T the devices are functionally identical. All models conform to 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. The indications for use statements are functionally identical. Please refer to the detailed comparison table presented below. The added models do not raise any new questions about safety or effectiveness.

| | K162651: Breast BI 7 MR Coil Mammavention 3T<br>K180123: Breast Bl 7 MR Coil 1.5T Mammavention | Breast BI Coil Set 0.55T;<br>Breast BI 7 MR Coil Set 1.5T;<br>Breast BI 7 MR Coil Set 3T | Comparison |
|---|---|---|---|
| Indication for Use | **K162651:** 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<br>**K180123**: 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 physican, 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 chan be performed by a trained physician.<br>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 | The intended use of the Breast Coil 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 placement of localization-wire by a trained physician. For use with Siemens 0.55T, 1.5T, and 3T systems | Functionally the same. An 0.55 T version has been added. |

| | **K162651: Breast BI 7 MR Coil Mammavention 3T**<br>**K180123: Breast Bl 7 MR Coil 1.5T Mammavention** | **Breast BI Coil Set 0.55T;**<br>**Breast BI 7 MR Coil Set 1.5T;**<br>**Breast BI 7 MR Coil Set 3T** | **Comparison** |
|---|---|---|---|
| Appearance |  |  | SIMILAR |
| MR Compatible Systems | 1.5 T or 3 T | 0.55 T, 1.5 T, 3 T depending on model chosen. | Wider compatibility |
| Standards | IEC 60601-1:2005, IEC 60601-1:2005 /AMD1:2012, Medical Electrical Equipment<br><br>IEC 60601-1-2:2014/ Electromagnetic disturbances - Requirements and tests<br><br>NEMA MS-1-2008 (R2020) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging<br><br>ISO 10993-5:2009 Biological evaluation of medical devices Cytotoxicity<br><br>ISO 10993-10:2009 Biological evaluation of medical devices Irritation and Sensitization<br><br>60601-1-6 Edition 3.1 2013-10 Collateral standard: Usability | Current versions used | SAME |
| Function | Employs a coil system which 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. | Identical mode of operation | SAME |
| Biocompatibility | Patient contact parts tested to ISO 10993 | SAME | SAME |

G) SUMMARY OF PERFORMANCE TESTING.
Patient contact materials were subjected to ISO 10993 tests for: Cytoxicity, Irritation, and sensitization. The devices were subjected to IEC60601-1 Safety Testing and IEC60601-1-2 ESD Testing.

Testing was performed to in accordance with NEMA MS 1-2008 (R2014, R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging in order to assure good S/N performance. Additionally, uniformity (NEMA MS 6-2008) and surface coil heating testing was successfully performed.

Usability testing was performed in accordance with: IEC 62366-1:2015 Medical Devices - Part 1: Application of Usability Engineering To Medical Devices IEC/TR 62366-2:2016 Medical Devices - Part 2: Guidance On The Application Of Usability Engineering To Medical Devices, and IEC 60601-1-6:2016 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability

Clinical sample test images were obtained for the new model listed above. The images exhibited good coverage, quality, uniformity and SNR.

H) CLINICAL TESTING: Not required.

I) CONCLUSION:
In all material aspects, the new models of breast MR coils performed equivalently to the predicate device, had similar construction methods, and have not raised any new issues of safety or effectiveness. They have an indications for use statement that is virtually identical to the predicate, thus rendering the new models of MRI coils substantially equivalent to the predicate.