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

July 26, 2017

LMT Medical Systems GmbH
% Mr. Thomas Plein
Manager Q&RA
Maria-Goeppert-Str. 5
Lubeck 23562
GERMANY

Re: K171515
Trade/Device Name: NHAC 16
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 7, 2017
Received: July 10, 2017

Dear Mr. Plein:

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.

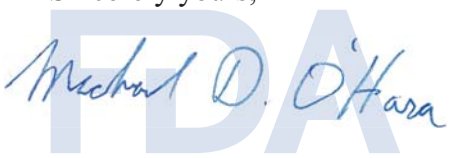
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 below.

510(k) Number *(if known)*
k171515

Device Name
NHAC 16

Indications for Use *(Describe)*
The NHAC 16 is a local coil (receive only) and is intended to be used in conjunction with 1.5T or 3.0T magnetic resonance imaging (MRI) systems by Philips or Siemens and can be used in conjunction with the MR Diagnostics Incubator System nomag® IC. It provides MR images of the neonatal head, non-invasively and without the use of ionizing radiation.

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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007-01

Special 510(k) Summary

I. SUBMITTER

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Contact Person: Thomas Plein
Title: Manager Quality & Regulatory Affairs
Email: regulatory@lmt-medicalsystems.com
Date prepared: May 19, 2017

II. DEVICE

Trade name:	NHAC 16
Classification name:	Magnetic Resonance Diagnostic Device
Product code:	MOS
Regulation number:	892.1000
Device Class:	II

III. PREDICATE DEVICE

Manufacturer:	LMT Medical Systems GmbH
Device name:	Neonate Array Coils
510(k) Number:	K091047

IV. DEVICE DESCRIPTION AND INTENDED USE

Indications for Use:
The NHAC 16 is a local coil (receive only) and is intended to be used in conjunction with 1.5T or 3.0T magnetic resonance imaging (MRI) systems by Philips or Siemens and can be used in conjunction with the MR Diagnostics Incubator System nomag® IC. It provides MR images of the neonatal head, non-invasively and without the use of ionizing radiation.

Description:
The NHAC 16 is a 16-channel coil (receive only) and is intended to produce high resolution images of the neonate head and brain.
The NHAC 16 serves solely as a receiving coil for the reception of high frequency signals from the hydrogen nuclei. The hydrogen nuclei are induced into precession by the transmitting coil of the MRT device. The precessing magnetization induces potential differences in the NHAC 16 which are processed by the MRT system.
Used in an MR Scanner or used in the MR Diagnostics Incubator System nomag® IC and an MR Scanner, the NHAC 16 is indicated for use as a diagnostic imaging device to provide transversal, sagittal, coronal and oblique images of the internal structures of the head.
When interpreted by a trained physician, these images provide information that can be useful in the determination of a diagnosis. The excited nucleus is 1H (Hydrogen).
The signal received by the coils is dependent upon the MRI parameters (T1 or spin-lattice relaxation time, T2 or spin-spin relaxation time, density of nuclei, flow velocity and chemical shift).

V. COMPARISON TO CLEARED DEVICE

The predicate device neonate array coils consists of:

- A 8-channel neonatal head array coil
- A 12-channel neonatal body array coil

The NHAC 16 is a 16-channel neonatal head array coil (NHAC) and a modification to the 8-channel neonatal head array coil. Therefore the following section will only compare the NHAC 16 to the 8-channel NHAC of the predicate device.

1. Electrical Design

The NHAC 16 has twice as much and smaller individual receive elements as the 8-channel NHAC which results in a higher SNR (signal-to-noise-ratio) of the NHAC 16. The overall length of the receive elements in z-direction of the coil is longer which results in a larger field-of-view.

2. Principles of operation

The scientific principles of operation (receiving coils for magnetic resonance imaging) are identical between the predicate and the modified device.

3. Mechanical Design

Principal cylindrical geometry is the same while the NHAC 16 has 1'' shorter width than the 8-channel NHAC. The NHAC 16 has a distinct shape at the upper side in feet-direction to improve the handling of patients with intubation. Depending on the MRI platform the NHAC 16 has two

connection cables instead of one. The overall weight has increased from 2.5kg for the 8-channel NHAC to 2.8kg for the NHAC 16.

4. Materials

The same materials are used in the construction of the predicate and the modified device.

5. Power supply

Both devices are supplied by the MRI as the energy source.

VI. TEST/PERFORMANCE DATA

General testing was performed to ensure that functional requirements were met and that the coil executes as expected. Performance testing was conducted using phantoms and accepted imaging quality metrics.

Since neonates are a vulnerable patient population, for this particular device, the benefits of sample clinical images did not outweigh the risks associated with acquisition of those images. Therefore substantial equivalence was determined based solely on phantom images and sample clinical images of the neonatal head were not necessary to support the premarket submission.

VII. CONCLUSIONS

As described in this summary, the modified device is substantially equivalent to the predicate device based on the analysis herein. The modified device raises no new concerns of safety or efficacy.