northh medical GmbH
℅ Kai-Kristoph Fehrs
Chief Quality Officer, QA/RA
Roentgenstrasse 24
22335 Hamburg
GERMANY

February 4, 2022

Re: K212271
Trade/Device Name: smart-sync
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: December 15, 2021
Received: December 28, 2021

Dear Kai-Kristoph Fehrs:

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); 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

CAPT Patrick Hintz, MSIH, CIH, USPHS
Associate 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)*
K212271

Device Name
smart-sync

Indications for Use *(Describe)*
smart-sync is intended to generate a gating signal for MR scanners (1.5T and 3T) for motion compensation by detecting the heartbeat of a patient using Doppler ultrasound. Thus, smart-sync is intended to improve the image quality by reducing movement artefacts for MR images of the whole body, where motion compensation of the heart movement is necessary.

smart-sync is intended to be used on pregnant women, where the fetus is examined. smart-sync is also intended to be used for adult MR examinations.

smart-sync is not intended to monitor any physiological parameters.

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

SUBMITTER INFORMATION

Establishment Name:	northh medical GmbH
Establishment Address:	Röntgenstr. 24 22335 Hamburg Germany
Company Phone:	+49 40 23969451
Company Fax:	Not available
Contact person:	Kai-Kristoph Fehrs Chief Quality Officer kf@northh.de
Organization Number:	624524
Date Summary Prepared:	2021-07-09

DEVICE IDENTIFICATION

Trade Name:	smart-sync
Common Name:	Ultrasound gating device for MRI scanners
Classification Name:	System, nuclear magnetic resonance imaging (892.1000, LNH, class 2)

PREDICATE AND REFERENCE DEVICES

Primary Predicate Device

smart-sync is substantially equivalent to the following primary predicate device:

Primary Predicate Device	Manufacturer	510(k) No	Clearance Date
High Impedance Cardiac Gating Cable	GE Medical Systems	K981190	06/30/1998

Additional Predicate Device

Due to technological differences to the primary predicate device, an additional predicate device is included in this submission.

Additional Predicate Device	Manufacturer	510(k) No	Clearance Date
Expression MR400 MRI Patient Monitoring System*	Invivo Corporation	K152330	12/23/2015

** The subject device is compared with the wireless ECG module of the Expression MR400.*

Reference Device

Due to a different acquisition method of the cardiac cycle, the following reference device is included in this submission.

Reference Device	Manufacturer	510(k) No	Clearance Date
Philips Avalon Fetal / Maternal Monitors FM20, FM30, FM40 and FM50	PHILIPS Medizin Systeme	K140535	11/25/2014

DEVICE DESCRIPTION

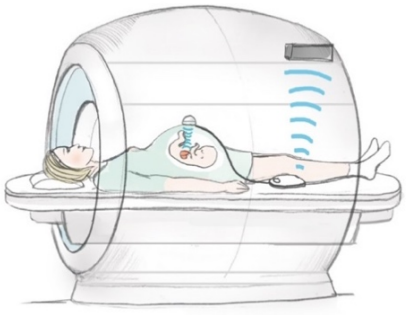

Figure 1: Fetal application

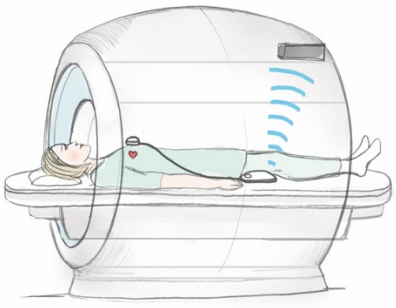

Figure 2: Adult application

smart-sync is an MRI-compatible Doppler ultrasound system that determines the cardiac cycle of patients and synchronizes it with the MRI imaging. *smart-sync* can be used for the synchronization of the heartbeat both for fetuses and adults.

The heartbeat of the patient is detected by positioning an ultrasound sensor above the patient's heart. The ultrasound sensor is fixated with a flexible belt. The reflection of Doppler ultrasound signals is analyzed, and a trigger signal is derived for every heartbeat. *smart-sync* sends the Doppler ultrasound signal and the trigger signal (synchronization signal) to the MRI scanner utilizing a wireless connection.

DISCUSSION - INDICATIONS FOR USE

The intended use of the subject device *smart-sync* and the primary predicate device *High Impedance Cardiac Gating Cable* can be summarized to "cardiac gating of the MRI scanner to reduce motion artifacts". Thus, the intended use of the subject device and the primary device are identical.

The additional predicate device *Expression MR400 Patient Monitoring System* is intended for monitoring and provides gating signals for MRI scanners. Thus, the additional predicate device includes a similar intended use "providing gating signals to the MRI scanner" as the subject device *smart-sync*.

The subject device and predicate devices are indicated for use by physicians to reduce motion artifacts for MR examinations.

Clinical tests and performance tests show that the subject device *smart-sync* is safe and effective for the intended patient population "fetuses in gestational age of week 30 and alter and for adults".

INTENDED USE

smart-sync is intended to generate a gating signal for MR scanners (1.5T and 3T) for motion compensation by detecting the heartbeat of a patient using Doppler ultrasound. Thus, *smart-sync* is intended to improve the image quality by reducing movement artefacts for MR images of the whole body, where motion compensation of the heart movement is necessary.

smart-sync is intended to be used on pregnant women, where the fetus is examined. *smart-sync* is also intended to be used for adult MR examinations.

smart-sync is not intended to monitor any physiological parameters.

Patient group

smart-sync is intended to be used on the following patient groups:

- Adults
- Pregnant women from their 30th gestational week where the fetus is being examined.

  Fetal movement in the early weeks of pregnancy might not make it possible to perform an MRI scan.

Indications

smart-sync is intended for MRI scans requested by doctors and where synchronization with the patient's heartbeat is required.

Contraindications

smart-sync is not intended for the following groups of people:

- *smart-sync* is not intended for people with MRI exclusion criteria such as cardiac pacemakers or implants.
- *smart-sync* is not intended for people with skin damage in the area where the ultrasound sensor is applied.

TECHNOLOGY CHARACTERISTICS

Characteristics	Subject Device	Primary Predicate Device	Additional Predicate Device
Device Name	smart-sync	High Impedance Cardiac Gating Cable	Expression MR400 MRI Patient Monitoring System
510(k) Number	N/A	K981190	K152330
Acquisition method	Doppler ultrasound	Electrocardiography	Electrocardiography
Measurement of cardiac cycle	myocardial wall and blood flow motion	R-Wave of ECG signal	R-Wave of ECG signal
MRI Safety Classification	MRI Conditional	MRI Conditional	MRI Conditional
Field Strength	1.5T and 3T	Up to 3T	Up to 3T
RF power levels	4 W / kg	4 W / kg	4 W / kg
Battery powered	Yes	No	Yes
Battery Type	Lithium Polymer	N/A	Lithium Polymer
Signal Transmission to MRI scanner	Wireless	Cable	Wireless

Characteristics	Subject Device	Primary Predicate Device	Additional Predicate Device
Frequency	2402–2482 MHz	N/A	2402–2482 MHz
Modulation Type	GFSK	N/A	GFSK
EIRP	4dBm (peak)	N/A	0dBm (peak)

The comparison of the technological charateristics shows that the characteristics of subject device *smart-sync* are identical or similar to the primary predicate device *High Impedance Cardiac Gating Cable* and to the wireless ECG module of the additional predicate device *Expression MR400 MRI Patient Monitoring System*, except for the acquisition method of the cardiac cycle. Technological differences shown are discussed and concluded to have no additional impact on safety and effectiveness or performance of the device.

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

The different acuisition method of the subject device *smart-sync* is compared with the reference device *Philips Avalon Fetal / Maternal Monitors FM20, FM30, FM40 and FM50*.

Characteristics	Subject Device	Reference Device
Device Name	smart-sync	Philips Avalon Fetal / Maternal Monitors FM20, FM30, FM40 and FM50
510(k) Number	N/A	K140535
Acquisition method	Doppler ultrasound	Doppler ultrasound
Measurement of cardiac cycle	myocardial wall and blood flow motion	myocardial wall and blood flow motion
MRI Safety Classification	MRI Conditional	MRI Conditional
Measurement Method	static pulsed Doppler (D)	static pulsed Doppler (D)
Measurement Range	Fetal: 60 – 240 BPM Adult: 30-120 BPM	50 to 240 bpm
Average output power	40kPa	(40.4 ± 4.3) kPa
Ultrasound Frequency	1,025 MHz ± 25 kHz	1 MHz ± 100 Hz
Ultrasound Burst - Repetition Rate	3.0 kHz	3.0 kHz
Ultrasound Burst - Duration	max 90 periods @ 1.025 MHz ≤ 100 µs	≤ 100 µs

The comparison of the acquisition method “Doppler ultrasound” shows that characteristics of the subject device *smart-sync* are identical or similar with the reference device *Philips Avalon Fetal / Maternal Monitors FM20, FM30, FM40 and FM50*.

A direct performance comparison of the subject device *smart-sync* and the predicate devices the *GE High impedance cardiac gating cable* and the wireless ECG module of the *Expression MR400 MRI Patient Monitoring System* is technically not possible. The predicate devices do not generate a comparable gating signal. An analytical comparison of the acquisition method shows that the same cardiac information can be derived from Doppler ultrasound as with electrocardiography.

As the subject device *smart-sync* and the predicate devices are gating devices for MRI scanners the device’s performance can be evaluated with the resulting MR image quality. Thus, the effectiveness of the subject device in improving the image quality for cardiac MR examination is provided in clinical tests.

The bench tests show that the subject device *smart-sync* is effective in providing gating signals for cardiac MR acquisition, which can be used by the MRI to improve the image quality. The bench tests also prove the safety of the subject device smart-sync and the compliance with applicable international safety and performance standards.

SUMMARY OF CLINICAL PERFORMANCE DATA

Clinical studies from clinicians at different hospitals across Europe and the US show that the subject device *smart-sync* is effective in improving the image quality for cardiac MRI examinations for the intended patient population “fetus in 30th week of gestation and adults”.

Usability tests show that the application of the subject device is safe to use for the intended user group radiographers and radiologists.

It is concluded that *smart-sync* is safe to use, and that *smart-sync* achieves its clinical performance to improve the image quality of MRI examinations for the intended patient population (pregnant women, where the fetus is examined in gestational age of week 30 and later, and for adults).

SUMMARY

The results of the substantial equivalence assessment, taken together with clinical evidence, non-clinical bench testing, electrical safety and electromagnetic compatibility, product verification and validation demonstrate that “smart-sync” does not raise different questions of safety and effectiveness when compared to the predicate devices “High Impedance Cardiac Gating Cable” and “Expression MR400 MRI Patient Monitoring System” and the reference device “Philips Avalon Fetal / Maternal Monitors FM20, FM30, FM40 and FM50”.

The provided data shows that smart-sync performs as intended, and has performance characteristics that are substantially equivalent to the predicate devices and that the different acquisition method Doppler ultrasound compared to the predicate device does not raise additional questions to safety and effectiveness.