NORAS MRI products GmbH
℅ Ms. Patricia Kirchner
Quality & Regulatory Affairs
Leibnizstr. 4
Hoechberg, Bavaria 97204
GERMANY

March 3, 2022

Re: K211658
Trade/Device Name: OR Head Holder LUCY with HeadCoilSet Siemens 1.5T, OR Head Holder LUCY with HeadCoilSet Siemens 3T, OR Head Holder LUCY with HeadCoilSet Philips 1.5T, OR Head Holder LUCY with HeadCoilSet Philips 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS, HBL
Dated: January 10, 2022
Received: January 12, 2022

Dear Ms. Kirchner:

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

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)*
K211658

Device Name
OR Head Holder LUCY with HeadCoilSet Siemens 1.5 T; OR Head Holder LUCY with HeadCoilSet Siemens 3T;
OR Head Holder LUCY with HeadCoilSet Philips 1.5T; OR Head Holder LUCY with HeadCoilSet Philips 3T;

Indications for Use *(Describe)*
The intended medical use of the OR Head Holder LUCY and Head Coil Set 1.5T/3T is, in conjunction with a Magnetic Resonance Scanner, intra-operative MR imaging during an open-skull neurosurgery.
The OR Head Holder LUCY is used for safe securing the patient's head during a surgical intervention at the head. It is possible to make an intraoperative assessment during the intervention to determine its progress. In the MR area the Head Coils enable the diagnostic imaging. Using Computed Tomography or C-arm Fluoroscopy, it is mandatory to remove the Head Coils and the device serves as a skull clamp only.

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

K211658

As required by section 807.92(c)

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

**Date Prepared:** March, 01 2021

**Manufacturer:**
NORAS MRI products GmbH
Leibnizstr. 4
97204 Hoechberg / Germany
Registration Number: 3004929307
Owner/Operator Number: 9071737

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**Device Name:**
OR Head Holder LUCY with HeadCoilSet Siemens 1.5 T
OR Head Holder LUCY with HeadCoilSet Siemens 3T
OR Head Holder LUCY with HeadCoilSet Philips 1.5T
OR Head Holder LUCY with HeadCoilSet Philips 3T

| | |
|---|---|
| **Trade Name**: | OR Head Holder LUCY with HeadCoilSet Siemens 1.5 T (Ref. 119734)<br>OR Head Holder LUCY with HeadCoilSet Siemens 3T (Ref. 119736)<br>OR Head Holder LUCY with HeadCoilSet Philips 1.5T<br>(Ref. 120281)<br>OR Head Holder LUCY with HeadCoilSet Philips 3T<br>(Ref. 120282) |
| **Common Name:** | OR Head Holder LUCY with HeadCoilSet Siemens 1.5 T<br>OR Head Holder LUCY with HeadCoilSet Siemens 3T<br>OR Head Holder LUCY with HeadCoilSet Philips 1.5T<br>OR Head Holder LUCY with HeadCoilSet Philips 3T |
| **Classification Panel:** | Radiology |
| **Regulation Number:** | 21 CFR § 892.1000 |
| **Device Class:** | II |
| **Product Code:** | MOS, HBL |

## 2. Safety and Effectiveness information supporting substantial equivalence

### Device Description

The OR Head Holder LUCY can be used for intra-operative MR Imaging, CT Imaging and C-arm Imaging. In use with the NORAS OR Head Coils 1.5T or 3T, the OR Head Holder LUCY can be applied for intra operative MR imaging during an open skull neurosurgery at human patients.

The NORAS OR Head Holder LUCY is used for safe fixation of the patient's head during neurosurgical procedures on the patient's skull with planning and resection aid for MRI, CT and C-arm Imaging.

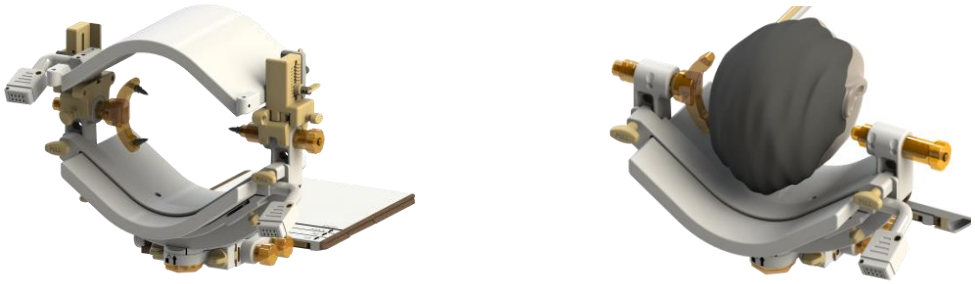

Image: Head Holder Set up with coils and fixed patient

One additional feature of the OR Head Holder LUCY is the ability of height adjustment providing an ideal patient positioning in 70 cm MRI (Siemens Magnetom Aera and Skyra and Philips Ingenia 1.5T/3T, Ingenia Ambition 1.5T and Ingenia Elition 3.0T) and in CT- Scanners. Furthermore, the whole set up can be moved parallel to the bore direction (in Z- direction).

The configuration allows comfortable positioning of the patient in prone, lateral or supine position on the transfer board and allows an exact adjustment of the Head Holder during the positioning of the patient´s head. The system supports awake craniotomy.

Mechanical, the model of the Head Holder allows a slight movement of both posts of the three-point fixation at the Arc with a stable geometry, which minimizes unwanted movements. The patients head will be fixed by three skull pins.

## Indications for use

The intended medical use of the OR Head Holder LUCY and Head Coil Set 1.5T/3T is, in conjunction with a Magnetic Resonance Scanner, intra-operative MR imaging during an open-skull neurosurgery.

The OR Head Holder LUCY is used for safe securing the patient’s head during a surgical intervention at the head. It is possible to make an intraoperative assessment during the intervention to determine its progress. In the MR area the Head Coils enable the diagnostic imaging. Using Computed Tomography or C-arm Fluoroscopy, it is mandatory to remove the Head Coils and the device serves as a skull clamp only.

## Substantial Equivalence

NORAS MRI products GmbH believes that, within the meaning of the Safe Medical Device Act of 1990, the OR Head Holder LUCY with Head Coil Set 1.5T/3T is substantially equivalent to the following Devices:

| Predicate Device Name and Manufacturer | 510(k) Number | Clearance Date | Product Code | Comparable Properties |
|---|---|---|---|---|
| NORAS OR Head Holder Flexibility<br>NORAS MRI products GmbH | K133506 | August 6, 2014 | MOS; HBL | Fixation of the patient´s head |
| MAYFIELD@ Infinity XR2 Skull Clamp<br>Integra LifeSciences Corporation | K130389 | April 23, 2013 | HBL | Fixation of the patient´s head and neck |

## Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

The OR Head Holder LUCY bears many similarities to its predicates, the NORAS OR Head Holder Flexibility and the MAYFIELD@ Infinity XR2 Skull Clamp. The OR Head Holder LUCY has the same indication for use as the predicate devices. All of them, the subject and the two predicate devices, are used for the fixation of the patient's head.

The NORAS OR Head Coil Set 1.5T and 3T can be used with both NORAS Head Holders, Flexibility and LUCY. The Coils were already registered with the FDA under the Premarket Submission Number K060758/K091546 and Listing Number E646984/D093265 by NORAS MRI Products GmbH.

The subject device offers the following improvements and minor differences over the predicate device "NORAS OR Head Holder Flexibility".

- The subject device can be used in Computed Tomography or C-arm Fluoroscopy
- The Subject device has other dimensional specifications. It is 330 mm less wide and deeper than the predicate device.
- The subject device is made of different materials than the predicate device.
- The subject device have a fixation only by three skull pins.

The subject device offers the following minor differences over the predicate device “Mayfield Infinity XR2 Skull Clamp”

- The subject device is made of different materials than the predicate device.
- The subject device uses NORAS or Brainlab Pins, Mayfield Infinity XR2 Skull Clamp uses only Mayfield Pins.
- The range of the force indicator of the subject device is higher (0-500N) than of the predicate device (0-356N).
- The subject device uses slightly different cleaning, disinfection and sterilization procedures.

**General Safety and Effectiveness Concerns**

The OR Head Holder LUCY combined with the NORAS OR Head Coil 1.5T/3T will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the DIN EN standards for safety issues with the Magnetic Resonance Imaging Devices (DIN EN 60601-2-33:2017). This will assure that the performance of this device can be considered safe and effective when used with the currently available Siemens Magnetom Aera 1.5T & Skyra 3T and Philips Ingenia 1.5T/3T, Ingenia Ambition 1.5T and Ingenia Elition 3.0T systems.

Risk management is ensured via a risk analysis in compliance with DIN EN ISO 14971:2013 to identify and provide mitigation to potential hazards in a risk analysis beginning early in the design phase and continuing throughout the development of the product. These risks are controlled via measures realized in development, testing and product labeling. To minimize risks, NORAS adhere to recognized and established industry practices and standards to minimize safety and performance risks. Furthermore, the operators and end users of the device are doctors or trained staff and responsible for other hospital procedures.

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

## Non-clinical Tests

Testing and analysis have been conducted to show that the verification, validation, and safety requirements have been met per the FDA as established standards. Risk Management is ensured via a risk analysis in compliance with DIN EN ISO 14971:2013 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. NORAS adhere to recognized and established industry standards, such as the DIN EN ISO 60601-1 series, to minimize electrical and mechanical hazards.

Non-clinical bench testing was conducted to support the intended use and to confirm that technological changes do not raise any new issues of safety or effectiveness over the predicate.

## Conclusion as to Substantial Equivalence

The subject device, OR Head Holder LUCY, is optimized for MRI, CT and C-arm supported surgery, just like the Mayfield Infinity XR2 Skull Clamp. While the other predicate device, NORAS OR Head Holder Flexibility, is optimized for its usefulness in interventional surgery applications. All three devices are Head Holders and the fundamental attributes of the subject device and the predicate devices are the same.

The conclusions from the non-clinical data suggest that the subject device has the same fundamental technological characteristics with respect to the predicate device and exhibits an equivalent safety and performance profile as that of the predicate device.

Following, NORAS MRI products GmbH believes, that the OR Head Holder LUCY with HeadCoilSet Siemens 1.5T/3T and HeadCoilSet Philips 1.5T/3T does not raise new questions of safety or effectiveness and, therefore, is substantially equivalent to the predicate devices listed above.