February 21, 2020

Pro Med Instruments GmbH
Sandra Untenberger
Regulatory Affairs Manager
Boetzinger Str. 38
Freiburg, 79111 DE

Re: K191740
Trade/Device Name: DORO LUCENT iXI and iMRI Headrest System
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: January 17, 2020
Received: January 22, 2020

Dear Sandra Untenberger:

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 Matthew Krueger
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191740

Device Name

DORO LUCENT® iXI and iMRI Headrest System

Indications for Use *(Describe)*

The DORO LUCENT radiolucent/MRI Compatible Headrest System with Skull Pins are components of a mechanical support system, which is used in cranial and spine surgery when rigid skeletal fixation is required for cranial stabilization and when intra-operative imaging is used.

The DORO LUCENT radiolucent/MRI Compatible Headrest System with noninvasive head positioning or noninvasive cranial stabilization device are components of a mechanical support system, which is used in cranial and spine surgery when noninvasive head positioning or noninvasive cranial stabilization is required and when intra-operative imaging is used.

The DORO LUCENT Headrest System provides an interface for accessories like retractor systems, navigation adaptors or other items.

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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pro med instruments GmbH
DORO LUCENT® iXI and iMRI Headrest System
510(k) Premarket Notification

DATE OF APPLICATION: 14.05.2019

APPLICANT:

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Position: Regulatory Affairs
Tel.: +49 761 384 222 45
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1 Device Name

Trade Name:	DORO LUCENT® iXI and iMRI Headrest System
Common Name:	Neurosurgical Head Holder (Skull Clamp)
Device Classification Name:	Holder, head, neurosurgical (Skull Clamp)

2 Classification / Product Code

DORO LUCENT® iXI and iMRI Headrest System can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Holder, head, neurosurgical (Skull Clamp)	Neurosurgical head holder (Skull Clamp)	Neurology	Neurology	HBL	882.44602	2

3 Predicate Device / Reference Device

Device	Predicate Device	510(k) Number	510(k) Holder
DORO LUCENT® iXI and iMRI Headrest System	DORO RADIOLUCENT HEADREST SYSTEM (ALSO MRI-COMPATIBLE) AND COMPONENTS	K063494	pro med instruments GmbH

4 Device Description

The DORO LUCENT® iXI and iMRI Headrest System ensures an adequate positioning of a patient's head for neurosurgery. Additional intra-operative imaging can be performed.

The DORO LUCENT® iXI and iMRI Headrest System consists of the following: Skull Clamp, Skull Pins, Parallelogram Adaptor and Headplate. The Parallelogram Adaptor is used to connect the Skull Clamp (including Skull Pins) or the Headplate to the OR-Table/ Transfer Board.

Additional accessories like the Adjusting wrench and Transfer Collision Indicator supports the performance of the Headrest System.

These special Headrest Systems are developed for selected OR-Table/ MRI scanner combinations. They are separated in following sets:

- 4003.200 DORO LUCENT® Headrest System TRUMPF for SIEMENS Aera/Skyra MRI Systems
- 4003.300 DORO LUCENT® iMRI Headrest System MAQUET for SIEMENS/PHILIPS/GE
- 4003.500 DORO LUCENT® iXI Headrest System

By the use of the Navigation Adaptors the performance of the Headrest System is supplemented. The intra-operative navigation is feasible because of the provided interface to the navigation device.

5 Intended Use

The DORO LUCENT radiolucent/MRI Compatible Headrest System with Skull Pins are components of a mechanical support system, which is used in cranial and spine surgery when rigid skeletal fixation is required for cranial stabilization and when intra-operative imaging is used.

The DORO LUCENT radiolucent/MRI Compatible Headrest System with noninvasive head positioning or noninvasive cranial stabilization device are components of a mechanical support system, which is used in cranial and spine surgery when noninvasive head positioning or noninvasive cranial stabilization is required and when intra-operative imaging is used.

The DORO LUCENT Headrest System provides an interface for accessories like retractor systems, navigation adaptors or other items.

6 Technological Characteristics

The Technological Characteristics of DORO LUCENT® iXI and iMRI Headrest System are the same as the Technological Characteristics of the predicate device.

	pro med instruments GmbH --- DORO LUCENT® iXI and iMRI Headrest System (New Device)	**pro med instruments GmbH --- DORO RADIOLUCENT HEADREST SYSTEM (ALSO MRI-COMPATIBLE) AND COMPONENTS (Predicate Device)**
Device Name	**DORO LUCENT® iXI and iMRI Headrest System**	**DORO RADIOLUCENT HEADREST SYSTEM (ALSO MRI-COMPATIBLE) AND COMPONENTS**
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
510(k) number	---	K063494

	pro med instruments GmbH --- DORO LUCENT® iXI and iMRI Headrest System (New Device)	**pro med instruments GmbH --- DORO RADIOLUCENT HEADREST SYSTEM (ALSO MRI-COMPATIBLE) AND COMPONENTS (Predicate Device)**
Indication for use	The DORO LUCENT radiolucent/MRI Compatible Headrest System with Skull Pins are components of a mechanical support system, which is used in cranial and spine surgery when rigid skeletal fixation is required for cranial stabilization and when intra-operative imaging is used. The DORO LUCENT radiolucent/MRI Compatible Headrest System with noninvasive head positioning or noninvasive cranial stabilization device are components of a mechanical support system, which is used in cranial and spine surgery when noninvasive head positioning or noninvasive cranial stabilization is required and when intra-operative imaging is used. The DORO LUCENT Headrest System provides an interface for accessories like retractor systems, navigation adaptors or other items.	**The Radiolucent/ MRI Compatible Skull Clamp Headrest System with Skull Pins** The DORO® Radiolucent/ MRI Compatible Skull Clamp Headrest System with Skull Pins are components of a mechanical support system which is used in head and neck surgery when rigid skeletal fixation is required for cranial stabilization and when intra-operative CT or MR Imaging is used. **The Radiolucent/ MRI Compatible Horseshoe Headrest System** The DORO® Radiolucent/ MRI Compatible Horseshoe Headrest System are components of a mechanical support system which is used in head and neck surgery when non-invasive head support is required and when intra-operative CT or MR Imaging is used. **The Radiolucent/ MRI Compatible Halo System** The DORO® Radiolucent/ MRI Compatible Halo System is a system of radiolucent halo rings of varying size and styles that may be used in neurosurgical applications as an arm rest during head and neck surgery when intra-operative CT or MR Imaging is required.
Principles of operation	Mechanical support system	Mechanical support system
Method of cranial stabilization	Rigid skeletal fixation or noninvasive stabilization	Rigid skeletal fixation or secured noninvasive stabilization
Method of cranial fixation	Three-point fixation in prone, supine or lateral position	Three-point fixation in prone, supine, lateral or sitting position
Method of noninvasive stabilization	Pad for prone or supine positioning	Non-invasive gel pad for prone or supine positioning
Intraoperative imaging	MR-, CT-, X-Ray- and Angiography-Imaging	MR-, CT- and X-Ray Imaging
reprocessing	Manual cleaning and disinfection between uses; single-use pins	Manual cleaning and disinfection between uses; single-use pins

	pro med instruments GmbH --- DORO LUCENT® iXI and iMRI Headrest System (New Device)	**pro med instruments GmbH --- DORO RADIOLUCENT HEADREST SYSTEM (ALSO MRI-COMPATIBLE) AND COMPONENTS (Predicate Device)**
	DORO® Skull Clamp radiolucent for DORO LUCENT® Parallelogram Adaptors	**DORO® Skull Clamp Radiolucent**
Sterility	Nonsterile	Nonsterile
Type of head fixation	3 point fixation	3 point fixation
Shape/ general design	U-shape	U-shape
Adjustment for various head sizes	Extension assembly is adjustable	Extension assembly is adjustable
Clamping force	Max. 360 N/ 80 lbs	Max. 360 N/ 80 lbs
Load range	Max. 12.5 kg/ 27.5 lbs	Max. 12.5 kg/ 27.5 lbs
Interface for accessories	Quick-Rail®	Quick-Rail®
Imaging modality	radiolucent, MR conditional (≤ 3T)	radiolucent, MR safe
Patient contact components/ materials	None	None
Materials:	polymers, glass, composites, metal coating	polymers, composites
	DORO LUCENT® Headplate	**DORO® Adult Horsehoe Headrest Radiolucent without Extension bar combined with DORO® Horseshoe Gel Pads (left & right)**
Sterility	Nonsterile	Nonsterile
Type of head fixation	Noninvasive	Noninvasive
Shape/ general design	Headplate base plate with foam pad	Horseshoe shaped base with gel-pads
Load range	Max. 12.5 kg/ 27.5 lbs	Max. 12.5 kg/ 27.5 lbs
Imaging modality	radiolucent, MR conditional (≤ 3T)	radiolucent, MR safe
Materials:	Polymers, composites	Polymers
	DORO LUCENT® Disposable Skull Pins, Adult, sterile	**DORO® Radiolucent Disposable Skull Pins, Ceramic, Adult**
Sterility	SAL 10^{-6} by gamma radiation	SAL 10^{-6} by ethylene oxide
Frequency of use	Single use	Single use
Packaging	Sterile blister pack	Sterile blister pack
Shape/ general design	Pin tip injected with plastic	Pin tip injected with plastic
Imaging modality	radiolucent, MR conditional (≤ 3T, SAR≤ 4W/kg)	radiolucent, MR safe
Materials	Metal, polymers, composite	Ceramic, polymers

	DORO LUCENT® Parallelogram Adaptor Trumpf for Siemens Aera/Skyra MRI systems	**DORO® Swivel Adaptor Radiolucent combined with DORO® Transitional Member Radiolucent (short and/or long)**
Sterility	Nonsterile	Nonsterile
Shape/ general design	A device that interfaces to the Skull Clamp on one side and the Transfer Board on the other, which is fixed to the OR-Table. The joint system in the parallelogram design combined with the joint for height adjustment, allows for the positioning adjustment in all degrees of freedom.	Different rods with interfaces to the Skull Clamp on one side and the OR-Table on the other side. The rods are connected with screws, wherein the positioning adjustment can be realized. The Swivel Adaptor is rotatable in his length axis.
Flexibility/ degrees of freedom	Linear axis (x): cranial/caudal-direction Linear axis (y): Lateral Linear axis (z): upwards/ downwards Rotation axes: around x-, y- and z-axis	Linear axis (x): cranial/caudal-direction Linear axis (y): Lateral Linear axis (z): upwards/ downwards Rotation axes: around x-, y- and z-axis
Load range	12.5 kg/ 27.5 lbs	12.5 kg/ 27.5 lbs
Interface OR-table	6 screws (M8) for attaching the adaptor on the Transfer Board (Trumpf OR-Table)	Starburst with screw (M16)
Interface Skull Clamp/ Head plate	Starburst with thread (M16)	Starburst with screw (M16)
Imaging modality	radiolucent, MR conditional (≤ 3T)	radiolucent, MR safe
Materials:	Polymers, composites, metal	Polymers, composite
	DORO LUCENT® iMRI Parallelogram Adaptor Maquet	**DORO® Swivel Adaptor Radiolucent combined with DORO® Transitional Member Radiolucent (short and/or long)**
Sterility	Nonsterile	Nonsterile
Shape/ general design	A device that interfaces to the Skull Clamp on one side and the Transfer Board on the other, which is fixed to the OR-Table. The joint system in the parallelogram design combined with the joint for height adjustment, allows for the positioning adjustment in all degrees of freedom.	Different rods with interfaces to the Skull Clamp on one side and the OR-Table on the other side. The rods are connected with screws, wherein the positioning adjustment can be realized. The Swivel Adaptor is rotatable in his length axis.
Flexibility/ degrees of freedom	Linear axis (x): cranial/caudal-direction Linear axis (y): Lateral Linear axis (z): upwards/ downwards Rotation axes: around x-, y- and z-axis	Linear axis (x): cranial/caudal-direction Linear axis (y): Lateral Linear axis (z): upwards/ downwards Rotation axes: around x-, y- and z-axis
Load range	12.5 kg/ 27.5 lbs	12.5 kg/ 27.5 lbs
Interface OR-table	4 screws (M18) for attaching the adaptor on the Transfer Board (Maquet OR-Table)	Starburst with screw (M16)

Interface Skull Clamp/ Head plate	Starburst with thread (M16)	Starburst with screw (M16)
Imaging modality	radiolucent, MR safe	radiolucent, MR safe
Materials:	Polymers, composites	Polymers, composite
	DORO LUCENT® iXI Parallelogram Adaptor Maquet	**DORO® Swivel Adaptor Radiolucent combined with DORO® Transitional Member Radiolucent (short and/or long)**
Sterility	Nonsterile	Nonsterile
Shape/ general design	A device that interfaces to the Skull Clamp on one side and the Transfer Board on the other, which is fixed to the OR-Table. The joint system in the parallelogram design combined with the joint for height adjustment, allows for the positioning adjustment in all degrees of freedom.	Different rods with interfaces to the Skull Clamp on one side and the OR-Table on the other side. The rods are connected with screws, wherein the positioning adjustment can be realized. The Swivel Adaptor is rotatable in his length axis.
Flexibility/ degrees of freedom	Linear axis (x): cranial/caudal-direction Linear axis (y): Lateral Linear axis (z): upwards/ downwards Rotation axes: around x-, y- and z-axis	Linear axis (x): cranial/caudal-direction Linear axis (y): Lateral Linear axis (z): upwards/ downwards Rotation axes: around x-, y- and z-axis
Load range	11 kg/ 24.25 lbs	12.5 kg/ 27.5 lbs
Interface OR-table	Slim plate with lateral rails to insert the adaptor in the Transfer Board (Maquet OR-Table) and clamping mechanism to protect pulling out the adaptor.	Starburst with screw (M16)
Interface Skull Clamp/ Head plate	Starburst with thread (M16)	Starburst with screw (M16)
Imaging modality	radiolucent, MR safe	radiolucent, MR safe
Materials	Polymers, composites	Polymers, composites

6.1 Summary of Technological Characteristics

The above listed Technological Characteristics show that the DORO LUCENT® iXI and iMRI Headrest System, and the DORO Radiolucent Headrest System (also MRI-compatible) and components are substantially equivalent. Therefore safety and effectiveness can be ensured for these items.

7 Performance Data

The devices have been tested as a system and single device. Tests were performed and the results are shown in the table below.

Test	Result
DORO LUCENT® iXI and iMRI Headrest System	
Static load Verifies the ability of the system to sustain a certain load with an additional safety factor.	**Pass** The System supports the static load plus the additional safety factor without mechanical failure.
MR-Compatibility Verifies the MR- Compatibility of the system.	**Pass** The system is MR compatible as it does not impair the function of the MRI system.
CT/Angio-Compatibility Verifies the CT/Angio- Compatibility of the system.	**Pass** The system is CT/Angio compatible, as there wasn't any new or additional shadowing on the image.
X-Ray-Compatibility Verifies the X-Ray- Compatibility of the system.	**Pass** The system is X-Ray compatible, as there wasn't any new or additional shadowing on the image.
DORO LUCENT® Skull Clamp	
Static load (Latching teeth mechanism) Verifies the ability of the Skull Clamp to sustain a certain load with an additional safety factor.	**Pass** The interface must withstand the static load over the defined duration without damage or malfunction.
Torque (Rocker Arm) Verifies the ability of the skull clamp to resist applied torque while in use.	**Pass** The Rocker Arm must withstand the torque without damaging, opening or malfunction of the Open-Lock mechanism.
DORO LUCENT® Skull Pins	
Mechanical stability (scratch test) Verifies the mechanical shear stability of the Skull Pin.	**Pass** The Skull Pin withstands an applied radial force when an axial force is applied.
MR-Compatibility Verifies the MR- Compatibility of the pin.	**Pass** The item is MR conditional.
Sterility Verifies the sterility of the pin.	**Pass** The tests show that the item is packaged sterile and stays sterile for the shelf life.
Biocompatibility Verifies the biocompatibility of the pin.	**Pass** The item is biocompatible.
DORO LUCENT® Headplate	
Static load Verifies the ability of the Headplate to sustain a certain load with an additional safety factor.	**Pass** The Headplate supports the static load plus safety factor without mechanical failure.
Biocompatibility Verifies the biocompatibility of the Headplate.	**Pass** The item is biocompatible.

Testing confirmed that the performance of the DORO LUCENT® iXI and iMRI Headrest System meets the product specification of the device.

8 Substantial Equivalence Summary / Conclusion

The DORO LUCENT® iXI and iMRI Headrest System and components are used as support to stabilize a patient's head during neurosurgical operative procedures.

This device is comparable in design, construction, intended use and performance characteristics to the predicate devices.

Based on available 510(k) information herein provided, DORO LUCENT® iXI and iMRI Headrest System and components are considered substantially equivalent to the predicate device in terms of intended use, technology and performance specifications. There are no differences between the devices which may raise new issues concerning safety or effectiveness.