April 24, 2024

Pro Med Instruments GmbH
Rabel Talpur
Regulatory Affairs Specialist
Bötzinger Straße 86
Freiburg, Baden-württemberg 79111
Germany

Re: K240319
Trade/Device Name: DORO LUCENT Skull Clamp (1101.001); DORO LUCENT Skull Clamp Pediatric Set (1101.040)
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: February 2, 2024
Received: February 2, 2024

Dear Rabel Talpur:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2024.04.24 13:21:24 -04'00'

Adam D. Pierce, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240319

Device Name
DORO LUCENT Skull Clamp (1101.001);
DORO LUCENT Skull Clamp Pediatric Set (1101.040)

Indications for Use *(Describe)*

The DORO LUCENT Skull clamp is part of a mechanical support system, which is used during head or neck surgery. The product can be used in an intra-operative setting for CT and X-ray imaging.

The DORO LUCENT Skull clamp Pediatric Set is part of a mechanical support system, which is used during head or neck surgery. The product can be used in an intra-operative setting for CT and X-ray imaging. The target patient population includes children over 5 years of age.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K240319

1 Device Information:

Category	**Comments**
Sponsor:	pro med instruments GmbH Bötzinger Straße 86 79111 Freiburg im Breisgau Germany Tel: + 49 (0) 761 384 222 10 Fax: +49 (0) 761 384 222 81 E-Mail: regulatoryaffairs@blackforestmedical.com
Correspondent Contact Information	Name: Rabel Talpur Position: Regulatory Affairs Specialist Tel.: + 49 (0) 761 384 222 67 E-Mail: regulatoryaffairs@blackforestmedical.com
Device Common Name:	Neurosurgical head holder (skull clamp)
Device Regulation & Name	882.4460, Neurosurgical head holder (skull clamp)
Classification & Product Code: 510(K) Number:	Device Classification: II Product Code: HBL 510(K) Number: K240319
Device Proprietary Name:	DORO LUCENT® Skull Clamp

2 Predicate Device Information:

Predicate Device	DORO LUCENT® iXI and iMRI Headrest System
Predicate Device Manufacturer:	pro med instruments GmbH
Predicate Device Common Name:	Neurosurgical head holder (skull clamp)
Predicate Device Premarket Notification #	K191740
Predicate Device Classification & Name	Device Class: II Holder, head, neurosurgical (Skull Clamp)
Predicate Device Classification & Product Code:	Device Class: II Product Code: HBL

3 Reference Device Information:

Reference Device	DORO® Headrest System
Reference Device Manufacturer:	pro med instruments GmbH
Reference Device Common Name:	Neurosurgical head holder (skull clamp)
Reference Device Premarket Notification #	K001808

Reference Device Classification & Name	Device Class: II Neurosurgical head holder (skull clamp)
Reference Device Classification & Product Code:	Device Class: II Product Code: HBL

4 Date Summary Prepared

24.04.2024

5 Device Description

The DORO LUCENT® Skull Clamp ensures an adequate positioning of a patient's head and provides rigid fixation for neurosurgery. The device is suitable for intra-operative X-ray and CT based imaging procedures.

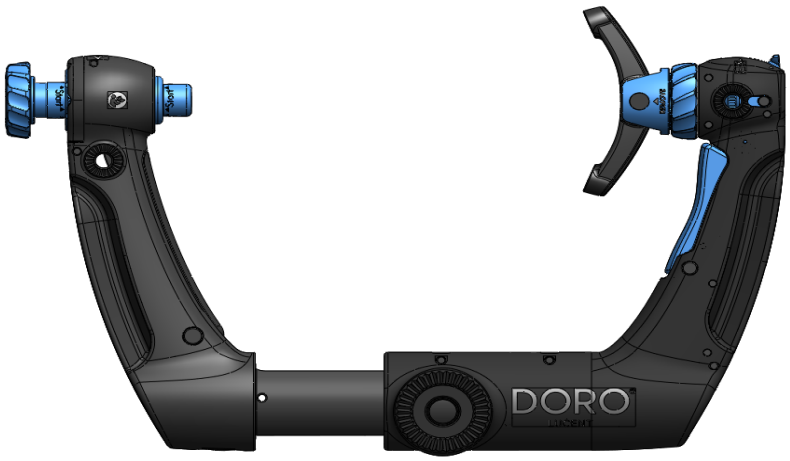

Figure 1: DORO LUCENT® Skull Clamp (REF: 1101.001)

The DORO LUCENT® Skull Clamp consists of a fixed arm, an adjustable arm and modular pin holders. Thus, using the DORO LUCENT® Skull Clamp Pediatric Set, the skull clamp can be configured as three-pin or four-pin pediatric set up.

Figure 2: DORO LUCENT® Skull Clamp pediatric Set (REF: 1101.040)

6 Indications for Use

The DORO LUCENT® Skull clamp is part of a mechanical support system, which is used during head or neck surgery. The product can be used in an intra-operative setting for CT and X-ray imaging.

The DORO LUCENT® Skull clamp Pediatric Set is part of a mechanical support system, which is used during head or neck surgery. The product can be used in an intra-operative setting for CT and X-ray imaging. The target patient population includes children over 5 years of age.

7 Comparison of the Technological Characteristics

Characteristic	**pro med instruments GmbH --- DORO LUCENT® Skull Clamp (K240319)**	**pro med instruments GmbH --- DORO LUCENT® iXI and iMRI Headrest System (K191740)**	**Impact on Substantial Equivalence**
Company	pro med instruments GmbH	pro med instruments GmbH	Substantially Equivalent
Regulation Number	882.4460	882.4460	Substantially Equivalent
Product Code	HBL	HBL	Substantially Equivalent
Intended Use	The DORO LUCENT® Skull clamp is part of a mechanical support system, which is used during head or neck surgery. The product can be used in an intra-operative setting for CT and X-ray imaging.	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.	Substantially Equivalent

Characteristic	pro med instruments GmbH --- DORO LUCENT® Skull Clamp (K240319)	pro med instruments GmbH --- DORO LUCENT® iXI and iMRI Headrest System (K191740)	Impact on Substantial Equivalence
Indications for Use	The DORO LUCENT® Skull clamp is part of a mechanical support system, which is used during head or neck surgery. The product can be used in an intra-operative setting for CT and X-ray imaging. The DORO LUCENT® Skull clamp Pediatric Set is part of a mechanical support system, which is used during head or neck surgery. The product can be used in an intra-operative setting for CT and X-ray imaging. The target patient population includes children over 5 years of age.	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.	Substantially Equivalent
Technology	Cranial fixation	Cranial fixation	Substantially Equivalent
Features:			
Principles of operation	Mechanical support system	Mechanical support system	Substantially Equivalent
Method of cranial stabilization	Rigid skeletal fixation	Rigid skeletal fixation or secured noninvasive stabilization	Substantially Equivalent
Method of cranial fixation	Three- and Four-point fixation in prone, supine or lateral position	Three-point fixation in prone, supine, lateral or sitting position	Substantially Equivalent
Intra-operative imaging	CT-, X-Ray Imaging	MR-, CT-, X-Ray- and Angiography-Imaging	Substantially Equivalent
reprocessing	Automated cleaning and disinfection between uses	Manual cleaning and disinfection between uses	Substantially Equivalent

7.1 Summary of Supporting Data

The above-listed Technological Characteristics show that the DORO LUCENT® Skull Clamp, and the DORO LUCENT® iXI and iMRI Headrest System are substantially equivalent.

8 Discussion of Performance Testing

Tests were performed and the results are shown in the table below.

Test	Result
DORO LUCENT® Skull Clamp	
Maximum Load Test (System Test) Verifies the skull clamp can resist the forces imposed by the patient and the surgeon when in use and in locked position.	**Pass** The skull clamp is capable to withstand given force without movement in any connection, joint and/or plastic deformation.
Usability Verifies if the usability of the skull clamp is given.	**Pass** The usability of skull Clamp is given
Static load (Latching teeth mechanism) Verifies the ability of the skull clamp to withstand maximum static load.	**Pass** The skull clamp withstands a static load for given duration without signs of permanent deformation, fracture, or breakage.
Creep Verifies the mechanical integrity of the Skull Clamp and its ability to withstand constant loading over time without a significant loss of clamping force.	**Pass** The skull clamp can maintain the applied maximum force without a force deviation from the initially applied load by a defined value.
Pin force accuracy Verifies the force delivery component to ensure the force readings are accurate and depict the actual force applied.	**Pass** The skull clamp force delivery component is verified at each force level throughout its range to deliver the stated force within the actual setting.
Torque load resistance Verifies skull clamp can withstand rotational movement when in use and locked position without impacting the locking mechanism.	**Pass** The skull clamp withstands a defined torque for given amount of time without deformation or any structural failures.
CT Evaluation Verifies that the skull clamp does not affects the CT images in a negative way and produce less artifacts according to the set benchmark for adequate imaging result.	**Pass** The skull Clamp produces less artefacts than the set benchmark as defined in the test report.

Reprocessing The reprocessing is done according to specifications that are defined in the instruction for use (IFU) of the product. The accumulation of residue evaluation, Cleaning effectiveness validation and Disinfection effectiveness validation is done according to: • ANSI / AAMI ST98:2022 – Cleaning validation of health care products – Requirements for development and validation of cleaning process for medical devices • DIN EN ISO 17664-1:2021 - Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices • DIN EN ISO 17664-2:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices. • AAMI TIR 12: 2020, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	**Pass** The tests data shows the reprocessing of DORO LUCENT® Skull Clamp is validated and test report in support to the statement is provided.

Testing confirmed that the performance of the DORO LUCENT® Skull Clamp meets the product specification of the device.

9 Conclusion

The DORO LUCENT® Skull Clamp is used as a head and neck 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 device and reference devices.

Based on available 510(k) information herein provided, DORO LUCENT® Skull Clamp is considered substantially equivalent to the predicate device in terms of intended use, technology and performance specifications, additional characteristic such as four-pin fixation is comparable to the reference device K001808.

There are no differences between the devices which may raise new issues concerning safety or effectiveness.