March 29, 2021

Pro Med Instruments GmbH
Muhammad Zubair
Regulatory Affairs Manager
Boetziger Str. 38
Freiburg, Bad Wuerttemberg 79111
Germany

Re: K203505
Trade/Device Name: DORO QR3 Headrest System (Aluminum)
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: February 15, 2021
Received: February 23, 2021

Dear Muhammad Zubair:

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,

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)*
K203505

Device Name
DORO QR3 Headrest System (Aluminum)

Indications for Use *(Describe)*
The DORO QR3 Headrest System is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.

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) SUBMISSION NUMBER: **K203505**

DATE: March 29, 2021

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1 Device Name

Trade Name:	*DORO® QR3 Headrest System*
Common Name:	*DORO® QR3 Headrest System (Aluminum)*
Device Classification Name:	Holder, head, neurosurgical (skull clamp)

2 Classification / Product Code

DORO QR3 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	882.4460	2

3 Predicate Device / Reference Device

Subject Device: DORO QR3 Headrest System (Aluminum)

Subject Device	Predicate Device	510(k) Number	510(k) Holder
DORO® QR3 Headrest System (Aluminum)	DORO RADIOLUCENT HEADREST SYSTEM AND HORSESHOE HEADRESTS,AND NON-RADIOLUCENT J-ARM RETRACTOR SYSTEM (ALUMINUM ALLOY)	K032331	Pro med instruments GmbH

4 Device Description

DORO® QR3 Headrest System consists of 3 components.

1. Skull clamp
2. Swivel Adapter
3. Adjustable Base Unit

4.1 DORO® QR3 Headrest System (Aluminum)

DORO® QR3 Headrest System (Aluminum) is a cranial stabilization device, designed to provide rigid skeletal fixation. The DORO Headrest System is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.

The Swivel Adaptor connects the Base Unit (by means of the Transitional Member) with the Skull Clamp. The Swivel Adaptor provides 360 degrees rotation. This allows a fully flexible adjustment of the DORO® Headrest System to the patient's position.

The Base Unit is designed for patient positioning in prone or supine, lateral and sitting positions.

5 Intended Use

The DORO® QR3 Headrest System (Aluminum) is a mechanical support system which is used in head and neck surgery. This system allows the patient's head to be positioned and

secured for the operation. It can be used for cranial fixation of the patient in prone, supine, lateral and sitting positions.

6 Technological Characteristics

The technological characteristics of DORO® QR3 Headrest System (Aluminum) are the same as the technological characteristics of the predicate device(s).

6.1 DORO QR3 Aluminum Headrest System

Device Name and 510k Submission number for Predicate or Subject Device	DORO® QR3 Aluminum Headrest System K203505	DORO Radiolucent Headrest System and Horseshoe Headrest and non-radiolucent J-Arm Retractors System K032331
Company name	pro med instruments GmbH	pro med instruments GmbH
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
Intended use	The DORO® QR3 Headrest System (Aluminum) is a mechanical support system which is used in head and neck surgery. This system allows the patient's head to be positioned and secured for the operation. It can be used for cranial fixation of the patient in prone, supine, lateral and sitting positions.	The DORO® Radiolucent Headrest System is used as a support mechanism for head and neck surgery. The DORO Non-Radiolucent J-Arm Retractor System is used as a component of the head and neck support during neurosurgical procedures to facilitate retraction of tissue is also required.
Indication for Use	The DORO® QR3 Headrest System is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.	Stabilization of head and neck during neurosurgical surgery through invasive or noninvasive fixation Support head and neck retraction of brain tissue and provide hand rest during neurosurgical surgery.
Material	Aluminum Stainless steel POM PTFE EPDM70	Novotex POM PEEK Polyurethan
Shape	Curved Uprights	Curved Uprights
Adjustment for various Head Sizes	Ratchet arm is adjustable	Ratchet arm is adjustable
Load Range	0-80 lbs	0-80 lbs
80lb force applicator	Yes	Yes
Three point fixation	Yes	Yes
2 pin	Yes	Yes
Chile Rocker Arm	No	No
Removable	No	No
Secured using the swivel lock knob	No	No
MR	Unsafe	Unsafe
Sterility	Non Sterile	Non Sterile
Swivel Adaptor		
Type of Head Fixation	Non Invasive	Non Invasive
Swivel Adapter Function	Connects Skull Clamp with Base Unit	Connects Skull Clamp with Base Unit
Sterility	Non Sterile	Non Sterile

Device Name and 510k Submission number for Predicate or Subject Device	DORO® QR3 Aluminum Headrest System K203505	DORO Radiolucent Headrest System and Horseshoe Headrest and non-radiolucent J-Arm Retractors System K032331
Company name	pro med instruments GmbH	pro med instruments GmbH
360° rotation under full impingement force	Yes	Yes
MR	Unsafe	Unsafe
Base Unit		
Type of Head Fixation	Non Invasive	Non Invasive
Base Unit Design	Connects the Headrest System to OP table	Connects the Headrest System to OP Table
Interface for accessories	Side Rail	Side Rail
Sterlity	Non Sterile	Non Sterile
MR	Unsafe	Unsafe
Target Patient Population	Not recommended for children under 5 years of age	Not recommended for children under 5 years of age
Cleaning /Decontamination	Intended to be used non-sterile. Intended to be cleaned by user between uses with manual pre -cleaning and washer disinfector according the process stated in the IFU.	Manual cleaning as stated in the IFU.
Operating environment	Used in the operating room of the hospital.	Used in the operating room of the hospital.
Compatibility with other DORO Products	DORO Skull Pins(Not part of this 510(k) Submission)	DORO Skull Pins

6.2 Summary of Technological Characteristics

DORO QR3 Headrest System is substantially equivalent in intended use, indication for use, dimensions and design to the predicate device(s).

7 Performance Data

The DORO® QR3 Headrest System have been tested as a system and single device. Tests were performed and the status of the results are shown in the table below.

Test	Result
DORO® QR3 Headrest System (Aluminum)	
1. System Test Test is performed in accordance with ASTM F3395 / F3395M-19.	Pass
2. Torque Load Resistance Test Test is performed in accordance with ASTM F3395 / F3395M-19.	Pass
3. Force Delivery Verification Test is performed in accordance with ASTM F3395 / F3395M-19	Pass
4. Creep Test Test is performed in accordance with ASTM F3395 / F3395M-19	Pass
5. Static Load Test is performed in accordance with ASTM F3395 / F3395M-19	Pass
6. Fourfold Load- Skull Clamp Test is performed in accordance with DIN EN 60601-2-46	Pass
7. Fourfold Load- Interface Skull Clamp to Swivel Adaptor Test is performed in accordance with DIN EN 60601-2-46	Pass
9. Usability Test Test is performed in accordance with EC 62366 as well as FDA-2011-D-0469	Pass
10. Automated cleaning including disinfection The test is performed in accordance with: EN ISO 15883-1:2014 – 10, RKI Guideline: 2012 Hygiene Requirements for the Reprocessing of Medical Devices, RKI Guideline: 2012 Hygiene Requirements for the Reprocessing of Medical Devices, AAMI TIR 30: 2011 as well as Guideline DGKH, DGSV, AKI: 2014 Leitlinie von DGKH, DGSV und AKI für die Validierung und Routineüberwachung maschineller Reinigungs- und thermischer Desinfektionsprozesse für Medizinprodukte	Pass

8 Substantial Equivalence Summary / Conclusion

DORO® QR3 Headrest System (Aluminum) is used together with the DORO® Skull Pins, intended as a neck and head support to stabilize the patient's head during neurosurgical procedures.

These devices are comparable in design, construction, intended use and performance characteristics to the predicate devices.

Based on available 510(k) information herein provided, DORO® QR3 Headrest System (Aluminum) is considered substantially equivalent to the predicate device(s) 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.