October 22, 2019

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

Re: K191979
Trade/Device Name: DORO QR3 XTom Headholder System
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: July 24, 2019
Received: July 24, 2019

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)*
K191979

Device Name

DORO® QR3 XTom Headholder System

Indications for Use *(Describe)*

The DORO® QR3 XTom Headholder System is 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 with a CT-Scanner is used.

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® QR3 XTom Headholder System
510(k) Premarket Notification

DATE OF APPLICATION: 19.07.2019

APPLICANT:

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CONTACT PERSON:

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

Trade Name:	DORO® QR3 XTom Headholder System
Common Name:	Neurosurgical Head Holder (Skull Clamp)
Device Classification Name:	Holder, head, neurosurgical (skull clamp)

2 Classification / Product Code

DORO® QR3 XTom Headholder 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

Device	Predicate Device	510(k) Number	510(k) Holder
DORO® QR3 XTom Headholder System	DORO RADIOLUCENT HEADREST SYSTEM AND COMPONENTS	K032331	pro med instruments GmbH

4 Reference Device

Device	Reference Device	510(k) Number	510(k) Holder
DORO® QR3 XTom Headholder System	DORO® Headrest System	K001808	pro med instruments GmbH

5 Device Description

The DORO® QR3 XTom Headholder System ensures an adequate positioning of a patient's head for neurosurgery. Due to the utilized material the device can be used for intra-operative CT imaging procedures.

The DORO® QR3 XTom Headholder System consists of the following: Skull Clamp, Skull Pins, Base Unit, Torque Screw Driver and U-Belt. The Base Unit is used to connect the Skull Clamp (including Skull Pins) to the OR-Table. A Headholder System is shown in Figure 1.

Figure 1: DORO® QR3 XTom Headholder System

Additional components like the Torque Screw Driver and U-Belt supports the performance of the Headholder System.

6 Intended Use

The DORO® QR3 XTom Headholder System is 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 with a CT-Scanner is used.

7 Technological Characteristics

The technological characteristics of DORO® QR3 XTom Headholder System are the same as the technological characteristics of the predicate device.

7.1 Device Characteristics Table

Company	**pro med instruments GmbH --- DORO® QR3 XTom Headholder System (New Device)**	**pro med instruments GmbH --- DORO® Radiolucent Headrest System and Horseshoe Headrest (Predicate Device)**
Device Name	**DORO® QR3 XTom Headholder System**	**DORO® Radiolucent Headrest System and Horseshoe Headrest**
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
510(k) number	---	K032331
Set Packaging	Case	Case
Item name	**DORO® QR3 XTom Skull Clamp**	**DORO® Skull Clamp Radiolucent**
Item number	**4002.001**	**3034-00**
Sterility	Nonsterile	Nonsterile
Reprocessing	Manual cleaning and disinfection between uses	Manual cleaning and disinfection between uses

Company	**pro med instruments GmbH --- DORO® QR3 XTom Headholder System (New Device)**	**pro med instruments GmbH --- DORO® Radiolucent Headrest System and Horseshoe Headrest (Predicate Device)**
Type of head fixation	3 point fixation	3 point fixation
Shape/ general design	U-shape with extension arms	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
Imaging modality	radiolucent	radiolucent
Patient contact components/ materials	None	None
Item name	**DORO® XTom Base Unit Parkbench**	**DORO® Skull Clamp Radiolucent**
Item number	**4002-10**	**3031-00**
Sterility	Nonsterile	Nonsterile
Reprocessing	Manual cleaning and disinfection between uses	Manual cleaning and disinfection between uses
Interface OR-table	OR table brackets with locking levers	OR table brackets with locking levers
Interface Skull Clamp	Starburst with thread	Starburst with screw
Adjustable Parts: height	Spindle can be moved up or down for height adjustment	Transitional members can be moved up or down for height
Adjustable Parts: height and lateral position	height and lateral position can be adjusted by moving the base handle assembly up or down	height and lateral position can be adjusted by moving the transitional members up or down
Adjustable Parts: Angulation	Angulation can be adjusted by moving the base Handle Assembly forward or backward Or by moving the spindle device sideways	Angulation can be adjusted by moving the swivel adaptor forward or backward Or by moving it sideways
Patient contact components/ materials	None	None
Materials:	Aluminum, stainless steel, synthetic material	Aluminum, stainless steel, synthetic material
Imaging	Base Unit is underneath the OR-table and therefore not in the imaging area	Base Unit is underneath the OR-table and therefore not in the imaging area

The DORO® QR3 XTom Headholder System uses the same DORO® Sterile Disposable Skull Pins, Stainless Steel, Adult (Item number 3006-00) as the reference device DORO® Headrest System (K001808).

7.2 Summary of Technological Characteristics

The above listed Technological Characteristics show that the DORO® QR3 XTom Headholder System, and the DORO Radiolucent Headrest System are substantially equivalent. Therefore safety and effectiveness can be ensured for these items.

8 Performance Data

The devices have been tested as a system and single device. Testing was performed using Skull Pins that were determined to be mechanically equivalent to the 3006-00 pins. Tests were performed and the results are shown in the table below.

Test	Result
DORO® QR3 XTom Headholder System	
System Test Verifies the ability of the system to sustain a certain load.	**Pass** The System supports the static load without mechanical failure.
Usability Verifies if the usability of the System is given.	**Pass** The usability of the System is given.
DORO® QR3 XTom 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.
Creep Test Verifies the mechanical integrity of the skull clamp and its ability to withstand loading over time without a significant loss of clamping force.	**Pass** The skull clamp must maintain the applied maximum force for a defined time without a force deviation from the initially applied load by a defined value.
Force delivery accuracy Verification Verifies the force delivery component of the skull clamp. This verification is intended to ensure the force readings are accurate and depict the actual force applied to the patient's skull.	**Pass** The skull clamp force delivery component must be verified at each major graduation throughout its range for a defined time to deliver the stated force within a defined range of the actual setting.
DORO® XTom U-Belt	
Dynamic load Verifies the ability of the Belt to sustain a certain dynamic load.	**Pass** The Belt must withstand the dynamic load without breakage or opening of the Belt.

Testing confirmed that the performance of the DORO® QR3 XTom Headholder System meets the product specification of the device.

9 Substantial Equivalence Summary / Conclusion

The DORO® QR3 XTom Headholder System 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® QR3 XTom Headholder System 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.