July 26, 2024

pro med instruments GmbH
Anja Krumm
Associate Regulatory Affairs Manager
Boetzinger Strasse 86
Freiburg, Baden-Württemberg 79111
Germany

Re: K241883
Trade/Device Name: DORO Sterile Disposable Skull Pins Stainless Steel, Adult (36 pcs) (3006-00); DORO Sterile Disposable Skull Pins Stainless Steel, Pediatric (36 pcs) (3006-10); DORO Sterile Disposable Skull Pin Titanium, Adult (36 pcs) (3006-20); DORO Sterile Disposable Skull Pin Titanium, Pediatric (36 pcs) (3006-30); DORO Sterile Disposable Skull Pin Stainless Steel, Adult (36 pcs) (3006-50)
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: June 28, 2024
Received: June 28, 2024

Dear Anja Krumm:

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: 2024.07.26 13:01:42 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241883

Device Name
DORO® Sterile Disposable Skull Pins Stainless Steel, Adult (3006-00); DORO® Sterile Disposable Skull Pins Stainless Steel, Pediatric (3006-10); DORO® Sterile Disposable Skull Pin Titanium, Adult (3006-20); DORO® Sterile Disposable Skull Pin Titanium, Pediatric (3006-30); DORO® Sterile Disposable Skull Pin Stainless Steel, Adult (3006-50)

Indications for Use *(Describe)*
Indicated for use in combination with a skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid 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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SUBMISSION NUMBER:	K241883
DATE:	07/26/2024
APPLICANT:	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
CONTACT PERSON:	E-Mail: info@blackforestmedical.com
	Name: Anja Krumm Position: Associate Regulatory Affairs Specialist Tel.: + 49 (0) 761 384 222 781 E-Mail: regulatoryaffairs@blackforestmedical.com

1 Device Name

Trade Name:	DORO Sterile Disposable Skull Pins Skull Pins
Common Name:	
Device Classification Name:	Holder, Head, Neurosurgical (Skull Clamp)

2 Classification / Product Code

DORO Sterile Disposable Skull Pins 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 1: DORO Sterile Disposable Skull Pins (Stainless Steel)

Subject Device	Predicate Device	510(k) Number	510(k) Holder
DORO® Sterile Disposable Skull Pins (Stainless Steel) Model: 3006-00 Stainless Steel, Adult, blue 3006-10 Stainless Steel, Pediatric, yellow 3006-50 Stainless Steel, Adult, black	DORO® Sterile Disposable Skull Pins	K193438	pro med instruments GmbH

Subject Device 2: DORO Sterile Disposable Skull Pins (Titanium)

Subject Device	Predicate Device	510(k) Number	510(k) Holder
DORO® Sterile Disposable Skull Pins (Titanium) Model: 3006-20 Titanium, Adult, orange 3006-30 Titanium, Pediatric, green	DORO® Sterile Disposable Skull Pins	K193438	pro med instruments GmbH

4 Device Description

DORO Sterile Disposable Skull Pins are disposable devices. These are delivered sterile (gamma-sterilization), ready for use, and are intended to be disposed after one use.

DORO Sterile Disposable Skull Pins are available in 2 different types (Stainless Steel & Titanium) and 2 different sizes (Adult & Pediatric).

4.1 DORO Sterile Disposable Skull Pins (Stainless Steel)

DORO Sterile Disposable Skull Pins (Stainless Steel) are used together with the DORO® Headrest Systems, intended as a neck and head support to stabilize the patient's head during neurosurgical procedures.

Two DORO Sterile Disposable Skull Pins are inserted into the rocker arm side of the skull clamp and one single skull pin is inserted in the opposite side.

4.2 DORO Sterile Disposable Skull Pins (Titanium)

DORO Sterile Disposable Skull Pins are used together with the DORO Headrest System, intended as a neck and head support to stabilize the patient's head during neurosurgical procedures.

Two DORO Sterile Disposable Skull Pins are inserted into the rocker arm side of the skull clamp and one skull pin is inserted in the opposite side.

DORO Sterile Disposable Skull Pins (Titanium) are used when Intra-Operative X-Ray-, CT- or MR-Imaging of the patient is used.

5 Intended Use

The DORO Sterile Disposable Skull Pin is utilized in a skull clamp and is applied to the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The skull clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.

6 Technological Characteristics

The technological characteristics of DORO® Sterile Disposable Skull Pins are the same as the technological characteristics of the predicate device.

6.1 DORO Sterile Disposable Skull Pins (Stainless Steel)

	pro med instruments GmbH --- DORO Sterile Disposable Skull Pins (Stainless Steel) (Subject Device)	**pro med instruments GmbH --- DORO Sterile Disposable Skull Pins (Stainless Steel) (K193438)**
Device Name	DORO Sterile Disposable Skull Pins (Stainless Steel)	**DORO Sterile Disposable Skull Pins (Stainless Steel)**
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
510(k) number	---	K193438
Intended Use	The DORO Sterile Disposable Skull Pin is utilized in a skull clamp and is applied to the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The skull clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.	The DORO Sterile Disposable Skull Pin is utilized in a skull clamp and is applied to the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The skull clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.
Indication for use	Indicated for use in combination with a skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.	Indicated for use in combination with a skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.
Material	Stainless Steel 1.4034 with a polymer base ABS	Stainless Steel 1.4034 with a polymer base PA6
Size	Adult Pediatric	Adult Pediatric
Tip Cone Angle	Adult: 35° Pediatric: 43°	Adult: 35° Pediatric: 43°
Tip Diameter	Adult: 0.21 Inches Pediatric: 0.18 Inches	Adult: 0.21 Inches Pediatric: 0.18 Inches
mounting shaft diameter	Adult: 0.31 inches Pediatric: 0.31 inches	Adult: 0.31 inches Pediatric: 0.31 inches
O-Ring	3006-00 Stainless Steel, Adult, Blue: No O-Ring 3006-10 Stainless Steel, Pediatric, Yellow: No O-Ring 3006-50 Stainless Steel, Adult, Black: O-Ring	3006-00 Stainless Steel, Adult, Blue: No O-Ring 3006-10 Stainless Steel, Pediatric, Yellow: No O-Ring 3006-50 Stainless Steel, Adult, Black: O-Ring

<table>
<tr><th></th><th>pro med instruments GmbH

DORO® Sterile Disposable Skull Pins
(Stainless Steel)
(Subject Device)</th><th>pro med instruments GmbH

DORO® Sterile Disposable Skull Pins
(Stainless Steel)
(K193438)</th></tr>
<tr><td>Manufacturing</td><td><table>
<tr><td>3006-00
Stainless Steel,
Adult, Blue

3006-10
Stainless Steel,
Pediatric, Yellow</td><td>The pin insert is machined according to the dimensions specified and cleaned afterwards. The Pin collet is injection-molded around the Pin insert in controlled environmental conditions.</td></tr>
<tr><td>3006-50
Stainless Steel,
Adult, Black</td><td>The pin insert is machined according to the dimensions specified and cleaned afterwards. Assembly of the O-Ring takes place in controlled environmental condition.</td></tr>
</table></td><td><table>
<tr><td>3006-00
Stainless Steel,
Adult, Blue

3006-10
Stainless Steel,
Pediatric, Yellow</td><td>The pin insert is machined according to the dimensions specified and cleaned afterwards. The Pin collet is injection-molded around the Pin insert in controlled environmental conditions.</td></tr>
<tr><td>3006-50
Stainless Steel,
Adult, Black</td><td>The pin insert is machined according to the dimensions specified and cleaned afterwards. Assembly of the O-Ring takes place in controlled environmental condition.</td></tr>
</table></td></tr>
<tr><td>Preparation for surgery</td><td>None, the pins are supplied sterile in a 3-pack blister ready for use</td><td>None, the pins are supplied sterile in a 3-pack blister ready for use</td></tr>
<tr><td>Method of Use</td><td>Typically, three pins are installed in receptacles of the head holder</td><td>Typically, three pins are installed in receptacles of the head holder</td></tr>
<tr><td>Clamp Compatibility</td><td>DORO Sterile Disposable Skull Pins are compatible with all the models of DORO brand skull clamps.</td><td>DORO Sterile Disposable Skull Pins are compatible with all the models of DORO brand skull clamps.</td></tr>
<tr><td>MR Compatibility</td><td>MR Unsafe</td><td>MR Unsafe</td></tr>
<tr><td>Method of Sterilization</td><td>Gamma Irradiation</td><td>Gamma Irradiation</td></tr>
<tr><td>Use</td><td>Disposable; Single-Patient Use only</td><td>Disposable; Single-Patient Use only</td></tr>
<tr><td>Packaging</td><td>Medical grade packaging (sealed TYVEK/Blister)</td><td>Medical grade packaging (sealed TYVEK/Blister)</td></tr>
</table>

6.2 DORO Sterile Disposable Skull Pins (Titanium)

	pro med instruments GmbH --- DORO Sterile Disposable Skull Pins (Titanium) (Subject Device)	**pro med instruments GmbH --- DORO Sterile Disposable Skull Pins (Titanium) (K193438)**
Device Name	DORO Sterile Disposable Skull Pins (Titanium)	**DORO Sterile Disposable Skull Pins (Titanium)**
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
510(k) number	---	K193438
Intended Use	The DORO Sterile Disposable Skull Pin is utilized in a skull clamp and is applied to the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The skull clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.	The DORO Sterile Disposable Skull Pin is utilized in a skull clamp and is applied to the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The skull clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.
Indication for use	Indicated for use in combination with a skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.	Indicated for use in combination with a skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.
Material	Titanium Grade 5 (Ti-6AI-4V) with a polymer base ABS	Titanium Grade 5 (Ti-6AI-4V) with a polymer base PA6
Size	Adult Pediatric	Adult Pediatric
Tip Cone Angle	Adult: 35° Pediatric: 43°	Adult: 35° Pediatric: 43°
Tip Diameter	Adult: 0.21 Inches Pediatric: 0.18 Inches	Adult: 0.21 Inches Pediatric: 0.18 Inches
mounting shaft diameter	Adult: 0.31 inches Pediatric: 0.31 inches	Adult: 0.31 inches Pediatric: 0.31 inches
O-Ring	3006-20 Titanium, Adult, Orange: No O-Ring 3006-30 Titanium, Pediatric, Green: No O-Ring	3006-20 Titanium, Adult, Turquoise: No O-Ring 3006-30 Titanium, Pediatric, Green: No O-Ring

	pro med instruments GmbH --- DORO Sterile Disposable Skull Pins (Titanium) (Subject Device)	pro med instruments GmbH --- DORO Sterile Disposable Skull Pins (Titanium) (K193438)
Manufacturing	3006-20 Titanium, Adult, Orange 3006-30 Titanium, Pediatric, Green: The pin insert is machined according to the dimensions specified and cleaned afterwards. The Pin collet is injection-molded around the Pin insert in controlled environmental conditions.	3006-20 Titanium, Adult, Turquoise 3006-30 Titanium, Pediatric, Green: The pin insert is machined according to the dimensions specified and cleaned afterwards. The Pin collet is injection-molded around the Pin insert in controlled environmental conditions.
Preparation for surgery	None, the pins are supplied sterile in a 3-pack blister ready for use.	None, the pins are supplied sterile in a 3-pack blister ready for use.
Method of Use	Typically, three pins are installed in receptacles of the head holder.	Typically, three pins are installed in receptacles of the head holder.
Clamp Compatibility	DORO® Sterile Disposable Skull Pins are compatible with all the models of Doro brand skull clamps.	DORO® Sterile Disposable Skull Pins are compatible with all the models of Doro brand skull clamps.
MR Compatibility	MR Conditional **Main magnetic field strength:** 1.5 Tesla or 3 Tesla **SAR:** Up to first level control mode (4 W/kg)	MR Conditional **Main magnetic field strength:** 1.5 Tesla or 3 Tesla **SAR:** Up to first level control mode (4 W/kg)
Method of Sterilization	Gamma Irradiation	Gamma Irradiation
Use	Disposable; Single-Patient Use only	Disposable; Single-Patient Use only
Packaging	Medical grade packaging (sealed TYVEK/Blister)	Medical grade packaging (sealed TYVEK/Blister)

6.3 Summary of Technological Characteristics

DORO Sterile Disposable Skull Pins (Stainless Steel & Titanium) are substantially equivalent in intended use, indication for use, dimensions and design to the predicate devices. Therefore, safety and effectiveness can be ensured for these items.

7 Performance Data

The DORO Sterile Disposable Skull Pins (Stainless steel & Titanium) have been tested as a system and single device. Tests were performed and the results are shown in the table below.

Test	Result
DORO Sterile Disposable Skull Pins (Stainless Steel & Titanium)	
Axial Load and Creep Test Confirms the ability of the skull pins to withstand typical loads w/ additional safety factor utilizing the worst-case product.	**Pass** The Pins are able to withstand typical static loads w/ additional safety factor w/o plastic deformation and an accepted distension.
Shear Test Confirms the ability of the skull pins and its interface with the cranial bone to withstand typical shear force w/ additional safety factor utilizing the worst-case product.	**Pass** The Pins are able to withstand typical shear force w/ additional safety factor w/o spatial locomotion.
Packaging System Performance and Stability Confirms the capability of the transport packing as well as the of product packaging to protect the skull pins against hazards, which may occur during handling, storage, and transport by air or ground. Confirms the capability of the sterile barrier system of the blister pack as well as the blister pack itself utilized for the skull pins whether it is effective, efficient and safe to use.	**Pass** The utilized packing system for the skull pins is capable to protect those against visible damage. The utilized sterile barrier system as well as the blister pack was proven to perform efficiently, safely, and effectively.
Interface Test Confirms safe and effective utilization of the skull pins w/ skull clamps w/o negative impact on utilized single-use gloves	**Pass** Skull Pins performer safely and effectively.
Biological Evaluation Confirms the biocompatibility of the skull pins by cytotoxicity test and chemical analysis of utilized materials.	**Pass** The skull pins obtain no cell growth inhibiting character. No chemical substance above harmful threshold was detected.
Color Coding Confirms the coloring of the plastic pin collets that enables the user to differentiate between MR conditional and MR unsafe skull pins as well as between skull pins for the adult population and pediatric population.	**Pass** Differentiation between designated patient populations as well as different applications is possible due to different colors utilized for the plastic pin collets.
Sterility Test Confirms the sterility of the skull pins as well as the maintained sterility of the skull pins at the end of the product's shelf life.	**Pass** VDmax validation as well as dye penetration test have proven the sterility of the product at delivery status as well as at the end of shelf life.

Test	Result
DORO Sterile Disposable Skull Pins (Titanium)	
MR-Safety Verifies the MR- Compatibility of the skull pins dedicated for the utilization in conjunction with MRT scanner utilizing the worst-case product.	**Pass** The skull pins are MR conditional.

Testing confirmed that the performance of the DORO® Sterile Disposable Skull Pins meets the product specification of the device.

8 Substantial Equivalence Summary / Conclusion

DORO Sterile Disposable Skull Pins (Stainless Steel & Titanium) are used together with the DORO Headrest System, 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 device K193438.

Based on available 510(k) information herein provided, DORO® Sterile Disposable Skull Pins are considered substantially equivalent to the predicate device K193438 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.