June 2, 2020

Pro Med Instruments GmbH
Muhammad Zubair
Regulatory Affairs Manager
Boetzinger Str. 38
Freiburg, 79111 De

Re: K193438
Trade/Device Name: DORO Sterile Disposable Skull Pins (Stainless Steel), DORO Sterile Disposable Skull Pins (Titanium)
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: April 29, 2020
Received: May 4, 2020

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.
Acting 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)*
K193438

Device Name
DORO Sterile Disposable Skull Pins (Stainless steel & Titanium)

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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DATE: June 2, 2020

DOCUMENT NUMBER: **K193438**

APPLICANT:

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1. Device Name

Trade Name:	DORO® Sterile Disposable Skull Pins
Common Name:	Skull Pins
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

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: 1. (3006-00 Stainless Steel, Adult, Blue) 2. (3006-50 Stainless Steel, Adult, Black)	TZ Skull Pin Adult	K163322	TZ Medical, Inc.
3. (3006-10 Stainless Steel, Pediatric, Yellow)	Mayfield Child Disposable Skull Pin	K941558	OHIO MEDICAL INSTRUMENT CO., INC.

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

Device	Predicate Device	510(k) Number	510(k) Holder
DORO® Sterile Disposable Skull Pins (Titanium) Model: 1. (3006-20 Titanium, Adult, Orange)	Limited Artifact Skull Pin	K073163	Dinkier Surgical Devices, Inc.
2. (3006-30 Titanium, Pediatric, Green)	Mayfield Child Disposable Skull Pin	K941558	OHIO MEDICAL INSTRUMENT CO., INC.

4. Device Description

DORO® Sterile Disposable Skull Pins are a disposable device. 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 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. Indications for Use

The DORO® Sterile Disposable Skull Pin is indicated for use in combination with a skull clamp 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)

Adult:

Company	**pro med instruments GmbH (New Device)**	**TZ Medical, Inc. (Predicate Device)**
Device Name	DORO® Sterile Disposable Skull Pins (Stainless steel)	TZ Skull Pin Adult
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
510(k) number	K193438	K163322
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 TZ Medical skull pin is placed in a 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 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 open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.
Material	Stainless Steel 1.4034 with a polymer base PA6	316L (1.4404) Stainless Steel
Size	Adult	Adult
Dimension		
Tip to Shoulder Distance	Adult: 0.5 Inches	Adult: 0.5 Inches
Width of back	Adult: 0.31 inches	Adult:0.31 inches
O-ring	3006-00 Stainless Steel, Adult, Blue: No O-Ring 3006-50 Stainless Steel, Adult, Black: Nitrile butadiene rubber (NBR) O-Ring	Silicone O-Ring

<table>
<tr><th>Company</th><th colspan="2">pro med instruments GmbH
(New Device)</th><th>TZ Medical, Inc.

(Predicate Device)</th></tr>
<tr><td>Manufacturing</td><td colspan="2"><table>
<tr><td>3006-00
Stainless Steel,
Adult, Blue</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 is machined according to the dimensions specified, and cleaned afterwards. Assembly of the O-ring takes place in controlled environmental conditions.</td></tr>
</table></td><td>The pin is machined to the dimensions specified. O-Ring is placed on device when manufacturing and cleaning is completed.</td></tr>
<tr><td>Preparation for surgery</td><td colspan="2">None, the pins are supplied sterile in a 3-pack pouch ready for use</td><td>None, the pins are supplied sterile in a 3-pack pouch ready for use</td></tr>
<tr><td>Method of Use</td><td colspan="2">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 colspan="2">DORO® Sterile Disposable Skull Pins are compatible with all the models of Doro brand skull clamps</td><td>V. Mueller Spetzler Skull Clamp-Model # M-1500
Integra Mayfield Skull Clamp- Model # A-1059
Integra Mayfield Skull Clamp- Model # A-2000</td></tr>
<tr><td>MR Compatibility</td><td colspan="2">MR Unsafe</td><td>MR Unsafe</td></tr>
<tr><td>Method of Sterilization</td><td colspan="2">Gamma Irradiation</td><td>Ethylene Oxide</td></tr>
<tr><td>Use</td><td colspan="2">Disposable; Single-Patient Use only</td><td>Disposable; Single-Patient Use only</td></tr>
<tr><td>Packaging</td><td colspan="2">Medical grade packaging (sealed TYVEK/Blister)</td><td>Medical grade packaging (sealed TYVEK/flexible film pouches)</td></tr>
</table>

Pediatric:

Company	pro med instruments GmbH (New Device)	OHIO MEDICAL INSTRUMENT CO., INC. (Predicate Device)
Device Name	DORO® Sterile Disposable Skull Pins (Stainless steel)	Mayfield Child Disposable Skull Pin
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
510(k) number	K193438	K941558
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.	Information not publically available in 510 (k) summary
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.	Information not publically available in 510 (k) summary
Recommended Age of use	The disposable skull pin is not intended for use on infants or children under 5 years of age.	The disposable skull pin is not intended for use on infants or children under 5 years of age.
Material	Stainless Steel 1.4034 with a polymer base PA6	Information not publically available in 510 (k) summary
Size	Pediatric	Pediatric
Dimension		
Tip to Shoulder Distance	Pediatric: 0.4 Inches	Information not publically available in 510 (k) summary
Width of back	Pediatric: 0.31 inches	Information not publically available in 510 (k) summary
O-ring	3006-10 Stainless Steel, Pediatric, Yellow: No O-Ring	Information not publically available in 510 (k) summary

Company	pro med instruments GmbH (New Device)	OHIO MEDICAL INSTRUMENT CO., INC. (Predicate Device)
Manufacturing	3006-10 Stainless Steel, Pediatric, Yellow: 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.	Information not publically available in 510 (k) summary
Preparation for surgery	None, the pins are supplied sterile in a 3-pack pouch ready for use	Information not publically available in 510 (k) summary
Method of Use	Typically , three pins are installed in receptacles of the head holder	Information not publically available in 510 (k) summary
Clamp Compatibility	DORO® Sterile Disposable Skull Pins are compatible with all the models of Doro brand skull clamps	Information not publically available in 510 (k) summary
MR Compatibility	MR Unsafe	Information not publically available in 510 (k) summary
Method of Sterilization	Gamma Irradiation	Information not publically available in 510 (k) summary
Use	Disposable; Single-Patient Use only	Information not publically available in 510 (k) summary
Packaging	Medical grade packaging (sealed TYVEK/Blister)	Information not publically available in 510 (k) summary

6.2. DORO® Sterile Disposable Skull Pins (Titanium)

Adult:

Company	pro med instruments GmbH (New Device)	Dinkier Surgical Devices, Inc. (Predicate Device)
Device Name	DORO® Sterile Disposable Skull Pins (Titanium)	Limited Artifact Skull Pin
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
510(k) number	K193438	K073163
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.	Limited Artifact Skull Pins are used with a head holder device that is placed on the patients'skull to hold their head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired.
Indication for Use	Indicated for use in combination with skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.	Indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and during intra-operative use within a MR environment rated up to and including a 1.5 Tesla magnetic Field
Material	Titanium Grade 5 (Ti-6AI-4V) with a polymer base PA6	The pin tip is Titanium 6Al-4V and the polymer base is PEEK with 10% carbon filler
Dimension		
Tip to Shoulder Distance	Adult: 0.5 Inches	Information not publically available in 510 (k) summary
Width of back	Adult: 0.31 inches	Information not publically available in 510 (k) summary
O-ring	3006-20 Titanium, Adult, Orange) / No O-Ring	O-Ring
Manufacturing	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.	The pin tip is machined to the dimensions listed on the pin tip drawing. The pin tip is injection molded to the dimensions listed on the pin base drawing.
Preparation for surgery	None, the pins are supplied sterile in a 3-pack pouch ready for use.	None, the pin are supplied sterile in a 3-pack pouch 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

Company	**pro med instruments GmbH (New Device)**	**Dinkier Surgical Devices, Inc. (Predicate Device)**
Clamp Compatibility	DORO® Sterile Disposable Skull Pins are compatible with all the models of Doro brand skull clamps	Information not publically available in 510 (k) summary
MR Compatibility	MR Conditional **Main magnetic field strength:** 1.5 Tesla or 3 Tesla	MR Conditional
Method of Sterilization	Gamma Irradiation	radiation sterilized
Use	Disposable; Single-Patient Use only	
Packaging	Medical grade packaging (sealed TYVEK/Blister)	Medical grade packaging (sealed TYVEK/flexible film pouches)

Pediatric

Company	pro med instruments GmbH (New Device)	OHIO MEDICAL INSTRUMENT CO., INC. (Predicate Device)
Device Name	DORO® Sterile Disposable Skull Pins (Titanium)	Mayfield Child Disposable Skull Pin
Regulation Number	882.4460	
Class	2	2
Code	HBL	HBL
510(k) number	K193438	K941558
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.	Information not publically available in 510 (k) summary
Indication for Use	Indicated for use in combination with skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.	Information not publically available in 510 (k) summary
Recommended Age of Use	The disposable skull pin is not intended for use on infants or children under 5 years of age.	The disposable skull pin is not intended for use on infants or children under 5 years of age.
Material	Titanium Grade 5 (Ti-6AI-4V) with a polymer base PA6	Information not publically available in 510 (k) summary
Size	Pediatric	Pediatric
Dimension		
Tip to Shoulder Distance	Pediatric: 0.4 Inches	Information not publically available in 510 (k) summary
Width of back	Pediatric: 0.31 inches	Information not publically available in 510 (k) summary
O-ring	3006-30 Titanium, Pediatric, Green: No O-Ring	Information not publically available in 510 (k) summary
Manufacturing	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.	Information not publically available in 510 (k) summary
Preparation for surgery	None, the pins are supplied sterile in a 3-pack pouch ready for use.	Information not publically available in 510 (k) summary
Method of Use	Typically , three pins are installed in receptacles of the head holder	Information not publically available in 510 (k) summary

Company	pro med instruments GmbH (New Device)	OHIO MEDICAL INSTRUMENT CO., INC. (Predicate Device)
Clamp Compatibility	DORO® Sterile Disposable Skull Pins are compatible with all the models of Doro brand skull clamps	Information not publically available in 510 (k) summary
MR Compatibility	MR Conditional **Main magnetic field strength:** 1.5 Tesla or 3 Tesla	Information not publically available in 510 (k) summary
Method of Sterilization	Gamma Irradiation	Information not publically available in 510 (k) summary
Use	Disposable; Single-Patient Use only	Information not publically available in 510 (k) summary
Packaging	Medical grade packaging (sealed TYVEK/Blister)	Information not publically available in 510 (k) summary

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.
Transport Validation 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.	**Pass** The utilized packing system for the skull pins is capable to protect those against visible damage.

Packing Integrity Test 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 sterile barrier system as well as the blister pack was proven to perform efficiently, safely, and effectively.
System Handling 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.
Input Materials Confirms the acceptance of utilized materials of the skull pins for medical use prior biocompatibility test.	**Pass** All utilized materials are accepted for medical use.
Biocompatibility Test 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-Compatibility 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. Conclusion: **Substantial Equivalence**

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 devices.

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