October 27, 2026

Black Forest Medical GmbH
Gabriel Siedle
Senior Regulatory Affairs Specialist
Boetzinger Strasse 86
Freiburg, 79117
Germany

Re: K262229
Trade/Device Name: DORO® Headrest System for AVA
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: September 29, 2026
Received: September 29, 2026

Dear Gabriel Siedle:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.10.27 17:46:40 -04'00'

for Ryan Trombetta, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262229

Please provide the device trade name(s).

DORO® Headrest System for AVA

Please provide your Indications for Use below.

The DORO Headrest System for AVA includes the following three skull clamp devices:
- DORO® UNITY Skull Clamp for AVA
- DORO® UNITY Skull Clamp
- DORO LUCENT® Skull Clamp for AVA

The DORO® UNITY Skull Clamp for AVA and the DORO® UNITY Skull Clamp is part of a mechanical support system, which is used during head or neck surgery.

The DORO LUCENT® Skull Clamp for AVA 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® AVA Sterile Disposable Skull Pins are indicated for use in combination with a skull clamp in open and percutaneous craniotomies, as well as spinal surgery, when rigid fixation is necessary.

The target patient population includes adults, adolescents and children over 5 years of age.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

DATE OF APPLICATION: 2026.06.30

APPLICANT:

Black Forest Medical 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: info@blackforestmedical.com

CONTACT PERSON:

Name: Dr. Gabriel Siedle

Position: Senior Regulatory Affairs Specialist

Tel.: + 49 (0) 761 384 222 54

E-Mail: regulatoryaffairs@blackforestmedical.com

BLACK FOREST MEDICAL GROUP

1 Device Name

Trade Name: DORO® Headrest System for AVA

Common Name: Neurosurgical Head Holder (Skull Clamp)

Device Classification Name: Holder, head, neurosurgical (Skull Clamp)

2 Classification / Product Code

The DORO® Headrest System for AVA 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® UNITY Skull Clamp for AVA

Subject Device	Predicate Device	Predicate Device 510(k) N°	510(k) Holder
DORO UNITY® Skull Clamp for AVA Models: 1010.001 DORO® UNITY Skull Clamp for AVA 1010.040 DORO® UNITY Pediatric Skull Pin Holder Set for AVA	DORO LUCENT® Skull Clamp	K240319	Pro med instruments GmbH

Subject Device 2: DORO® UNITY Skull Clamp

Subject Device	Predicate Device	510(k) Number	510(k) Holder
DORO® UNITY Skull Clamp Models: 1015.001 DORO® UNITY Skull Clamp 1015.040 DORO® UNITY Pediatric Skull Pin Holder Set	DORO LUCENT® Skull Clamp	K240319	Pro med instruments GmbH

Subject Device 3: DORO LUCENT® Skull Clamp for AVA

Subject Device	**Predicate Device**	**510(k) Number**	**510(k) Holder**
DORO® UNITY Skull Clamp Models: 1110.001 DORO LUCENT® Skull Clamp for AVA 1110.040 DORO LUCENT® Skull Clamp Pediatric Skull Pin Holder Set for AVA	DORO LUCENT® Skull Clamp	K240319	Pro med instruments GmbH

Subject Device 4: DORO® AVA Disposable Skull Pins, Stainless Steel

Subject Device	**Predicate Device**	**510(k) Number**	**510(k) Holder**
DORO® AVA Disposable Skull Pins, Stainless Steel Models: 1006.000 DORO® AVA Disposable Skull Pins, Stainless Steel, 3-Pin (Adult/Pediatric) 1006.010 DORO® AVA Disposable Skull Pins, Stainless Steel, 4-Pin (Pediatric)	DORO® Sterile Disposable Skull Pins	K193438	Pro med instruments GmbH

Subject Device 5: DORO® AVA Disposable Skull Pins, Titanium

Subject Device	**Predicate Device**	**510(k) Number**	**510(k) Holder**
DORO® AVA Disposable Skull Pins, Titanium Models: 1106.020 DORO® AVA Disposable Skull Pins, Titanium, 3-Pin (Adult/Pediatric) 1106.030 DORO® AVA Disposable Skull Pins, Titanium, 4-Pin (Pediatric)	DORO® Sterile Disposable Skull Pins	K193438	Pro med instruments GmbH

Subject Device 6: DORO LUCENT® AVA Disposable Skull Pins

Subject Device	**Predicate Device**	**510(k) Number**	**510(k) Holder**
DORO LUCENT® AVA Disposable Skull Pins Models: 1106.120/121 DORO LUCENT® AVA Disposable Skull Pins, 3-Pin (Adult/Pediatric) 1106.130 DORO LUCENT® AVA Disposable Skull Pins, 4-Pin (Pediatric)	DORO LUCENT® iXI and iMRI Headrest System	K191740	Pro med instruments GmbH

4 Device Description

The DORO® Headrest System for AVA ensures adequate positioning of a patient's head and provides rigid fixation for neurosurgery.

The DORO® Headrest System for AVA consists of the following:

- *DORO® UNITY Skull Clamp for AVA* with Pediatric Set and corresponding *DORO® AVA Skull Pins* from Stainless Steel
- *DORO® UNITY Skull Clamp* with Pediatric Set for use with commercially available *DORO® Skull Pins*
- *DORO LUCENT® Skull Clamp for AVA* with Pediatric Set with corresponding *DORO® AVA Skull Pins (Titanium)* and *DORO LUCENT® AVA Skull Pins (Titanium/PEEK)* for intra-operative X-ray and CT based imaging procedures.

Each DORO® Skull Clamp consists of a fixed arm, an adjustable arm and modular pin holders. Each Skull Clamp can be configured as three-pin or four-pin pediatric set up.

An overview of the separate components is provided in "Device list, Section 4" of 003_Comprehensive Device Description and Principles of Operation.

4.1 DORO® UNITY Skull Clamp for AVA

The DORO® UNITY Skull Clamp for AVA is designed to be used with DORO® AVA Disposable Skull Pins, Stainless Steel.

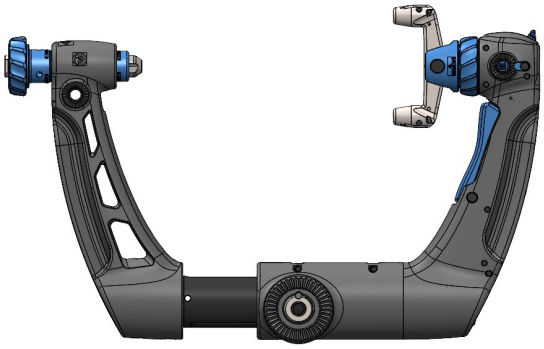


Figure 1: DORO® UNITY Skull Clamp for AVA (REF:1010.001)

Using the DORO® UNITY Pediatric Skull Pin Holder Set for AVA, the skull clamp can be configured as three-pin or four-pin pediatric set up.

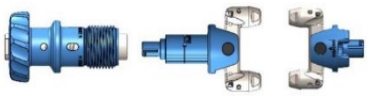


Figure 2: DORO® UNITY Pediatric Skull Pin Holder Set for AVA (REF: 1010.040)

4.2 DORO® UNITY Skull Clamp

The DORO® UNITY Skull Clamp and the corresponding Pediatric Skull Pin Holder Set can be used with standard skull pins.

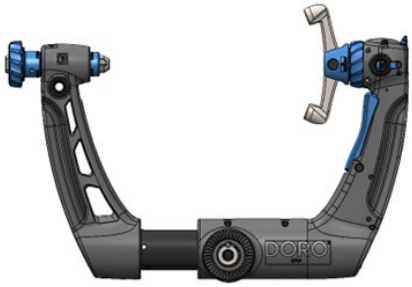


Figure 3: DORO® UNITY Skull Clamp (REF:1015.001)

Using the DORO® UNITY Pediatric Skull Pin Holder Set, the skull clamp can be configured as three-pin or four-pin pediatric set up for use with standard skull pins.



Figure 4: DORO® UNITY Pediatric Skull Pin Holder Set for AVA (REF: 1015.040)

4.3 DORO LUCENT® UNITY Skull Clamp for AVA

This DORO LUCENT® Skull Clamp for AVA and the corresponding Pediatric Skull Pin Holder Set can be used with DORO® AVA skull pins.



Figure 5: DORO LUCENT® Skull Clamp for AVA (REF:1110.001)

Using the DORO LUCENT® Pediatric Skull Pin Holder Set, the skull clamp can be configured as three-pin or four-pin pediatric set up for use with standard skull pins.

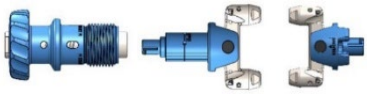


Figure 6: DORO® UNITY Pediatric Skull Pin Holder Set for AVA (REF: 1110.040)

4.4 DORO® AVA Disposable Skull Pins, Stainless Steel

DORO® AVA Disposable Skull Pins, Stainless Steel are used together with the DORO® Skull Clamp for AVA intended as a neck and head support to stabilize the patient's head during neurosurgical procedures.

Two DORO® AVA Disposable Skull Pins, Stainless Steel are inserted into the rocker arm side of the skull clamp. A single skull pin is inserted on the opposite side. The pins used on the rocker arm side feature a distinctly shaped tip compared to those used on the single-pin side.

4.5 DORO® AVA Disposable Skull Pins, Titanium

DORO® AVA Disposable Skull Pins, Titanium, are used together with the DORO LUCENT® Skull Clamp for AVA, intended as a neck and head support to stabilize the patient's head during neurosurgical procedures.

Two DORO® AVA Disposable Skull Pins, Titanium, are inserted into the rocker arm side of the skull clamp. A single skull pin is inserted on the opposite side. The pins used on the rocker arm side feature a distinctly shaped tip compared to those used on the single-pin side.

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

4.6 DORO LUCENT® AVA Disposable Skull Pins

DORO LUCENT® AVA Disposable Skull Pins are used together with the DORO LUCENT® Skull Clamp for AVA, intended as a neck and head support to stabilize the patient's head during neurosurgical procedures.

Two DORO LUCENT® AVA Disposable Skull Pins are inserted into the rocker arm side of the skull clamp. A single skull pin is inserted on the opposite side. The pins used on the rocker arm side feature a distinctly shaped tip compared to those used on the single-pin side

DORO LUCENT® AVA Disposable Skull Pins are used when intra-operative X-Ray-, CT- or MR-Imaging of the patient is used.

5 Intended Use/Indications for Use

The DORO® UNITY Skull clamp for AVA and the DORO® UNITY Skull clamp is part of a mechanical support system, which is used during head or neck surgery.

The DORO LUCENT® Skull clamp for AVA 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® AVA Sterile Disposable Skull Pins are indicated for use in combination with a skull clamp in open and percutaneous craniotomies, as well as spinal surgery, when rigid fixation is necessary.

The target patient population includes adults, adolescents and children over 5 years of age.

6 Technological Characteristics

The technological characteristics of the DORO® Headrest System for AVA are the same as the technological characteristics of the predicate device. The new device consists of the following articles:

6.1 DORO® UNITY Skull Clamp for AVA

	Black Forest Medical GmbH **---** **DORO® Headrest System for AVA** **(New Device)**	**pro med instruments GmbH** **---** **DORO LUCENT® Skull Clamp** **(Predicate Device)**
Article Name	**DORO® UNITY Skull Clamp for AVA**	**DORO LUCENT® Skull Clamp**
510(k) number	---	K240319
Regulation Number	882.4460	882.4460

	Black Forest Medical GmbH **---** **DORO® Headrest System for AVA** **(New Device)**	**pro med instruments GmbH** **---** **DORO LUCENT® Skull Clamp** **(Predicate Device)**
Class	2	2
Code	HBL	HBL
Intended Use	The DORO® UNITY Skull clamp for AVA is part of a mechanical support system, which is used during head or neck surgery. The DORO® UNITY Pediatric Skull Pin Holder Set for AVA is part of a mechanical support system, which is used during head or neck surgery. The target patient population includes children over 5 years of age.	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.
Indication for use	The DORO® UNITY Skull clamp for AVA is part of a mechanical support system, which is used during head or neck surgery. The target patient population includes adults, adolescents and children over 5 years of age.	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.
Principles of operation	Mechanical support system	Mechanical support system
Method of cranial stabilization	Rigid skeletal fixation	Rigid skeletal fixation
Method of cranial fixation	Three- and four-point fixation in prone, supine or lateral position	Three- and four-point fixation in prone, supine or lateral position
Intraoperative imaging modalities	Non-imaging procedures	Non-imaging procedures as well as CT- and X-Ray-Imaging
Materials	Polymers and metals	Polymers
Biological Characteristics	Not in body contact	Not in body contact
Reprocessing	Automated cleaning and disinfection between uses	Automated cleaning and disinfection between uses

	Black Forest Medical GmbH **---** **DORO® Headrest System for AVA** **(New Device)**	**pro med instruments GmbH** **---** **DORO LUCENT® Skull Clamp** **(Predicate Device)**
Sterility	Non-sterile	Non-sterile
Type of head fixation	Three- and four-point fixation	Three- and four-point fixation
Shape / general design	U-shape	U-shape
Clamping force	Max. 360N/ 80 lbs	Max. 360N/ 80 lbs
Load range	Max. 12.5 kg/ 27.5 lbs	Max. 12.5 kg/ 27.5 lbs

6.2 DORO® UNITY Skull Clamp

	Black Forest Medical GmbH **---** **DORO® Headrest System for AVA** **(New Device)**	**pro med instruments GmbH** **---** **DORO LUCENT® Skull Clamp** **(Predicate Device)**
Article Name	**DORO® UNITY Skull Clamp**	**DORO LUCENT® Skull Clamp**
510(k) number	---	K240319
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
Intended Use	The DORO® UNITY Skull clamp is part of a mechanical support system, which is used during head or neck surgery. The DORO® UNITY Pediatric Skull Pin Holder Set is part of a mechanical support system, which is used during head or neck surgery. The target patient population includes children over 5 years of age.	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.

	Black Forest Medical GmbH **---** **DORO® Headrest System for AVA** **(New Device)**	**pro med instruments GmbH** **---** **DORO LUCENT® Skull Clamp** **(Predicate Device)**
Indication for use	The DORO® AVA Skull clamp is part of a mechanical support system, which is used during head or neck surgery. The target patient population includes adults, adolescents and children over 5 years of age.	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.
Principles of operation	Mechanical support system	Mechanical support system
Method of cranial stabilization	Rigid skeletal fixation	Rigid skeletal fixation
Method of cranial fixation	Three- and four-point fixation in prone, supine or lateral position	Three- and four-point fixation in prone, supine or lateral position
Intraoperative imaging modalities	Non-imaging procedures	Non-imaging procedures as well as CT- and X-Ray-Imaging
Materials	Polymers and metals	Polymers
Biological Characteristics	Not in body contact	Not in body contact
Reprocessing	Automated cleaning and disinfection between uses	Automated cleaning and disinfection between uses
Sterility	Non-sterile	Non-Sterile
Type of head fixation	Three- and Four-point fixation	Three- and Four-point fixation
Shape / general design	U-shape	U-shape
Clamping force	Max. 360N/ 80 lbs	Max. 360N/ 80 lbs
Load range	Max. 12.5 kg/ 27.5 lbs	Max. 12.5 kg/ 27.5 lbs

6.3 DORO LUCENT® Skull Clamp for AVA

	Black Forest Medical GmbH **---** **DORO® Headrest System for AVA** **(New Device)**	**pro med instruments GmbH** **---** **DORO LUCENT® Skull Clamp** **(Predicate Device)**
Article Name	**DORO LUCENT® Skull Clamp for AVA**	**DORO LUCENT® Skull Clamp**
510(k) number	---	K240319
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
Intended Use	The DORO LUCENT® Skull clamp for AVA is part of a mechanical support system, which is used during head or neck surgery. The DORO LUCENT® Pediatric Skull Pin Holder Set for AVA is part of a mechanical support system, which is used during head or neck surgery. The target patient population includes children over 5 years of age.	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.
Indication for use	The DORO LUCENT® Skull clamp for AVA 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 adults, adolescents and children over 5 years of age.	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.
Principles of operation	Mechanical support system	Mechanical support system
Method of cranial stabilization	Rigid skeletal fixation	Rigid skeletal fixation
Method of cranial fixation	Three- and four-point fixation in prone, supine or lateral position	Three- and four-point fixation in prone, supine or lateral position

	Black Forest Medical GmbH **---** **DORO® Headrest System for AVA** **(New Device)**	**pro med instruments GmbH** **---** **DORO LUCENT® Skull Clamp** **(Predicate Device)**
Intraoperative imaging modalities	CT-, X-Ray Imaging	CT-, X-Ray Imaging
Materials	Polymers	Polymers
Biological Characteristics	Not in body contact	Not in body contact
Reprocessing	Automated cleaning and disinfection between uses	Automated cleaning and disinfection between uses
Sterility	Non-sterile	Non-Sterile
Type of head fixation	Three- and Four-point fixation	Three- and Four-point fixation
Shape / general design	U-shape	U-shape
Clamping force	Max. 360N/ 80 lbs	Max. 360N/ 80 lbs
Load range	Max. 12.5 kg/ 27.5 lbs	Max. 12.5 kg/ 27.5 lbs
Imaging modalities	radiolucent	radiolucent

6.4 DORO® AVA Disposable Skull Pins, Stainless Steel

	Black Forest Medical GmbH **---** **DORO® AVA Disposable Skull Pins, Stainless Steel** **(Subject Device)**	**pro med instruments GmbH** **---** **DORO® Sterile Disposable Skull Pins, Stainless Steel** **(K193438)**
Article Name	**DORO® AVA Disposable Skull Pins, Stainless Steel**	**DORO® Sterile Disposable Skull Pins (Stainless Steel)**
510(k) number	---	K193438
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL

	Black Forest Medical GmbH **---** **DORO® AVA Disposable Skull Pins, Stainless Steel** **(Subject Device)**	**pro med instruments GmbH** **---** **DORO® Sterile Disposable Skull Pins, Stainless Steel** **(K193438)**
Intended Use	The DORO® AVA Sterile Disposable Skull Pins are utilized in a skull clamp and are applied to the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired.	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 1.4542	Stainless Steel 1.4034 with a polymer base ABS
Biological Characteristics	Invasive, Externally communicating medical device (Tissue/bone/dentin) Limited duration ≤ 24h	Invasive, Externally communicating medical device (Tissue/bone/dentin) Limited duration ≤ 24h
Dimension		
Diameter front section	Min 4.5 mm	Min 4.5 mm (metal part of article 3006-10)
Cone angle (pin tip)	2 x 30°, 1 x 50° (3-Pin Configuration) 4 x 30° (pediatric 4-Pin configuration)	3 x 38° (adult 3-pin configuration) 4 x 43° (pediatric 4-pin configuration)
Manufacturing	The pin is machined according to the dimensions specified and cleaned. In the last step a tip protection sleeve is attached	The pin insert is machined according to the dimensions specified and cleaned. Assembly of the O-Ring takes place in controlled environmental conditions. (Article 3006-50) In the last step a tip protection sleeve is attached.
Preparation for surgery	None; the pins are supplied sterile in a 3-pack blister/4-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/four pins (pediatric set) are installed in receptacles of the head holder	Typically, three pins/four pins (pediatric set) are installed in receptacles of the head holder
Clamp Compatibility	DORO® AVA Skull Pins are compatible with all the models of DORO® for AVA brand skull clamps.	DORO® Sterile Disposable Skull Pins are compatible with all the models of DORO® brand skull clamps.
MR Compatibility	MR Unsafe	MR Unsafe

	Black Forest Medical GmbH --- DORO® AVA Disposable Skull Pins, Stainless Steel (Subject Device)	**pro med instruments GmbH --- DORO® Sterile Disposable Skull Pins, Stainless Steel (K193438)**
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)

6.5 DORO® AVA Disposable Skull Pins, Titanium

	Black Forest Medical GmbH --- DORO® AVA Disposable Skull Pins, Titanium (Subject Device)	**pro med instruments GmbH --- DORO® Sterile Disposable Skull Pins, Titanium (K193438)**
Device Name	DORO® AVA Disposable Skull Pins , Titanium	**DORO® Sterile Disposable Skull Pins (Titanium)**
510(k) number	---	K193438
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
Intended Use	The DORO® AVA Disposable Skull Pins are utilized in a skull clamp and are applied to the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired.	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)	Titanium Grade 5 (Ti-6AI-4V) with a polymer base PA6
Biological Characteristics	Invasive, Externally communicating medical device (Tissue/bone/dentin) Limited duration ≤ 24h	Invasive, Externally communicating medical device (Tissue/bone/dentin) Limited duration ≤ 24h
Dimension		

	Black Forest Medical GmbH **---** **DORO® AVA Disposable Skull Pins, Titanium** **(Subject Device)**	**pro med instruments GmbH** **---** **DORO® Sterile Disposable Skull Pins, Titanium** **(K193438)**
Diameter front section	Min 4.5 mm	Min 4.5 mm (metal part of article 3006-30)
Total length	31.8 mm	36.35 mm (adult) 30.35 (pediatric)
Cone angle (pin tip)	2 x 30°, 1 x 50° (3-Pin Configuration) 4 x 30° (pediatric 4-Pin configuration)	3 x 38° (adult 3-pin configuration) 4 x 43° (pediatric 4-pin configuration)
Manufacturing	The pin is machined according to the dimensions specified and cleaned. In the last step a tip protection sleeve is attached	The pin insert is machined according to the dimensions specified and cleaned. The Pin collet is injection-molded around the Pin insert in controlled environmental conditions. In the last step a tip protection sleeve is attached.
Preparation for surgery	None; the pins are supplied sterile in a 3-pack blister/4-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/four pins (pediatric set) are installed in receptacles of the head holder	Typically, three pins/four pins (pediatric set) are installed in receptacles of the head holder
Clamp Compatibility	DORO® AVA Skull Pins are compatible with all the models of DORO® for AVA brand skull clamps.	DORO® Sterile Disposable Skull Pins are compatible with all the models of DORO® brand skull clamps.
MR Compatibility	MR conditional (≤ 3T, SAR≤ 4W/Kg)	MR conditional (≤ 3T, SAR≤ 4W/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)

6.6 DORO LUCENT® AVA Disposable Skull Pins

	Black Forest Medical GmbH --- DORO LUCENT® AVA Disposable Skull Pins (Subject Device)	**pro med instruments GmbH --- DORO LUCENT® Sterile Disposable Skull Pins, Adult, (K191740)**
Device Name	**DORO LUCENT® AVA Disposable Skull Pins**	**DORO LUCENT® Disposable Skull Pins, Adult, sterile**
510(k) number	---	K191740
Regulation Number	882.4460	882.4460
Class	2	2
Code	HBL	HBL
Intended Use	The DORO® AVA Disposable Skull Pins are utilized in a skull clamp and are applied to the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired.	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 intraoperative imaging is used.
Material	Titanium Grade 5 (Ti-6AI-4V) PEEK CF30 schwarz	Titanium Grade 5 (Ti-6AI-4V) PEEK CF30 Black Natural Rubber (NBR)
Dimension		
Diameter front section	6.5 mm	5.02 mm
Total length	31.8 mm (for 1 Pin Side) 31.54 mm (for Rocker Arm Side)	32.0 mm
Cone angle (pin tip)	2 x 30°, 1 x 50° (3-Pin Configuration) 4 x 30° (pediatric 4-Pin Configuration)	3 x 40° (adult 3-pin configuration)
Manufacturing	The Pin Tip (Jacket) is machined according to the dimensions specified and cleaned. The Pin Body is injection-molded into the Pin Jacket in controlled environmental conditions. In the last step a tip protection sleeve is attached.	The pin tip (Jacket) is machined according to the dimensions specified and cleaned. The Pin Body is injection-molded into the Pin Jacket in controlled environmental conditions. In the last step, an O-Ring is mounted, and a tip protection sleeve is attached.
Preparation for surgery	None; the pins are supplied sterile in a 3-pack blister/4-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/four pins (pediatric set) are installed in receptacles of the head holder	Typically, three pins are installed in receptacles of the head holder

	Black Forest Medical GmbH **---** **DORO LUCENT® AVA Disposable Skull Pins** **(Subject Device)**	**pro med instruments GmbH** **---** **DORO LUCENT® Sterile Disposable Skull Pins, Adult,** **(K191740)**
Clamp Compatibility	DORO® AVA Skull Pins are compatible with all the models of DORO® AVA brand skull clamps.	DORO® Sterile Disposable Skull Pins are compatible with all the models of DORO® brand skull clamps.
MR Compatibility	MR conditional (≤ 3T, SAR≤ 4W/Kg)	MR conditional (≤ 3T, SAR≤ 4W/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)

6.7 Summary of Technological Characteristics

The components of the DORO® Headrest System for AVA are substantially equivalent in intended use, dimensions and design to the predicate devices. Therefore, safety and effectiveness can be ensured for these items.

7 Performance Data

The DORO® Headrest System for AVA has been tested as a system and single device. Tests were performed and the results are shown in the table below.

Test	Result
DORO® Skull Clamp (all models)	
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 affect the CT images in a negative way and produces 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.
DORO® and DORO LUCENT® AVA Disposable Skull Pins (all models)	
Axial Load Test Confirms the ability of the skull pins to withstand typical loads w/ additional safety factor utilizing the worst-case product.	**Pass** The Pins can 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 can withstand typical shear force w/ additional safety factor w/o spatial locomotion.
Usability Verifies if the usability of the skull pins is given.	**Pass** The usability of skull clamp is given.
Packaging System Performance and Stability Confirms the capability of the transport packaging as well as the 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.
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.
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.
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** DORO® AVA Disposable Skull Pins, Stainless Steel: n/a (The skull pins are MR unsafe) DORO® AVA Disposable Skull Pins, Titanium; DORO LUCENT® AVA Disposable Skull Pins: The skull pins are MR conditional.

Testing confirmed that the performance of the DORO® Headrest System for AVA meets the product specification of the device.

8 Claims

The FDA MedWatch safety communication regarding neurosurgical skull clamps, issued on February 25, 2016, highlighted a critical risk of device slippage or unintended displacement prior to or during surgical interventions. This phenomenon poses a significant hazard, as it may result in inadvertent head movement and subsequent patient injury.

In response to this safety concern, our organization initiated a comprehensive research program to systematically investigate the mechanisms underlying slippage and unintended movement in neurosurgical applications involving skull clamp systems.

Our new DORO® AVA product series is based on the findings of this research, and leads to the following claims:

- Preclinical testing on mixed-gender cadaveric specimens, aged 63–102 years, under clinically relevant loads, showed for our novel pinning system >50% reduced slippage at 347 N (clinically relevant procedures including simulated trepanation) and 35% reduced slippage at 520 N (1.5-fold safety margin above clinical loads).
- Preclinical testing on mixed gender cadaveric specimens from elderly donors, confirmed more homogeneous penetration depth of our novel pinning system across all three skull pin entry points in prone position, middle fossa, and pterional approach compared to status quo pinning systems.
- The streamlined pin geometry offers a slim profile, shoulder-free design, and no protruding surfaces. It is designed to minimize localized tissue compression and associated pressure-related injury.
- Head phantom testing in bifrontal craniotomy confirmed our novel pinning system showed 44% lower displacement during loading and 40% lower displacement after unloading versus standard configurations, potentially reducing navigation inaccuracy in systems without continuous cranial position monitoring, though results may differ in cadaveric specimens and other craniotomy approaches.

9 Substantial Equivalence Summary / Conclusion

The DORO® / DORO LUCENT® Skull Clamps and DORO® / DORO LUCENT® Skull Pins are used as head and neck support to stabilize a patient's head during neurosurgical operative procedures. The devices are comparable in design, construction, intended use and performance characteristics to the predicate devices.

Based on available 510(k) information herein provided, DORO® / DORO LUCENT® Skull Clamps and DORO® / DORO LUCENT® AVA Skull Pins are considered substantially equivalent to the predicate devices K240319 (Skull Clamps) and K193438/K191740 (Skull Pins) 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.