November 6, 2025

Medical Bees GmbH
% Angelika Scherp
Regulatory Affairs Consultant
Business Support International
Aalsmeerweg 123-3
Amsterdam, NH 1059AH
Netherlands

Re: K250423
Trade/Device Name: mb-FIX Cranial Stabilization Systems
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: October 10, 2025
Received: October 10, 2025

Dear Angelika Scherp:

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.

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 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: 2025.11.06 08:32:13 -05'00'

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)*
K250423

Device Name
mb-FIX Cranial Stabilization Systems

Indications for Use *(Describe)*
The mb-FIX Cranial Stabilization System Skull Clamps (Gold Standard Head Holding System, Premium Head Holding System and CT/MRI-compatible Head Holding System) are placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamps and pins are indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.
The CT/MRI-compatible model and the Titanium or PEEK + Titanium Skull Pins are used when intra-operative imaging is required.
The mb-FIX Cranial Stabilization System provides an interface for accessories like retractor systems or navigation adaptors or other items.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Date: November 4, 2025

Submitter:	Name:	Medical Bees GmbH
	Address:	Friedrich-Woehler-Strasse 13, 78576 Emmingen-Liptingen, Germany
	Contact Person:	Reinhold Bücher Senior Manager Quality Management and Regulatory Affairs
	Email:	ra@medical-bees.de
Product:	Name of Device:	mb-FIX Cranial Stabilization System
	Classification:	HBL Skull Clamp, Reg. No. 882.4460
		HBM Neurosurgical Headrest, Reg. No. 882.4440
Predicate Devices:	K142238	Mayfield Skull Clamp
	K072208	MAYFIELD Disposable and Reusable Titanium Skull Pins
Reference Devices:	K191740	DORO LUCENT iXI and iMRI Headrest System
	K941558	Mayfield Disposable Stainless Steel Pin (Child)
	K193438	DORO Disposable Skull Pin Pediatric
	K163322	TZ Skull Pin Adult

Device Description:

mb-FIX Cranial Stabilization Systems include three models of skull clamp:

- Gold Standard Head Holding System
- Premium Head Holding System
- CT/MRI-compatible Head Holding System

Each Head Holding System consists of a skull clamp and a base unit permitting attachment to an operating table.

The device includes four skull pin models, each provided in two sizes, one for adults and one for children. The skull pins are manufactured of stainless steel, titanium, PEEK + stainless steel or PEEK + titanium. The skull pins containing stainless steel are MR Unsafe devices. The skull pins manufactured of titanium or of PEEK + titanium are MR Conditional devices

The CT/MRI-compatible Head Holding System is MR Safe and can be used in combination with the titanium or PEEK + titanium skull pins when intra-operative imaging is required.

The Gold Standard and Premium Head Holding Systems are MR Unsafe.

The mb-FIX Cranial Stabilization System provides an interface for accessories like retractor systems, navigation adaptors or other items.

Indications for Use:

The mb-FIX Cranial Stabilization System Skull Clamps (Gold Standard Head Holding System, Premium Head Holding System and CT/MRI-compatible Head Holding System) are placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamps and pins are indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.

The CT/MRI-compatible model and the Titanium or PEEK + Titanium Skull Pins are used when intra-operative imaging is required.

The mb-FIX Cranial Stabilization System provides an interface for accessories like retractor systems, navigation adaptors or other items.

Technological Characteristics:

The technological and performance characteristics of the subject device are the same as those of the predicate devices, as shown by the following summary table:

	Subject Device	*Predicate Device*
Manufacturer	Medical Bees Gmbh	Integra LifeSciences Corporation
Product Name	mb-FIX Cranial Stabilization Systems Skull Clamps	Mayfield Skull Clamp
Common Name	Skull Clamp	Skull Clamp
Classification Regulation	882.4460	882.4460
510(k) Number	K250423	K142238
Indications for Use	The mb-FIX Cranial Stabilization System Skull Clamps (Gold Standard Head Holding System, Premium Head Holding System and CT/MRI- compatible Head Holding System) are placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamps and pins are indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary. The CT/MRI-compatible model and the Titanium or PEEK + Titanium Skull Pins are used when intra-operative imaging is required. The mb-FIX Cranial Stabilization System provides an interface for accessories like retractor systems, navigation adaptors or other items.	The MAYFIELD Skull Clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.
Design and Operating principle	The mb-FIX Cranial Stabilization System Skull Clamps are a cranial stabilization device, designed to provide rigid skeletal fixation. The mb-FIX Cranial Stabilization System Skull Clamps support a 2-pin rocker arm, which allows for 360° rotation under full impingement force. The device has the means for skull pin force determination via an integral force gauge in the torque screw opposite the rocker arm. The device is equipped with an adjustable arm to allow the surgeon to adjust the clamp for various head sizes. The mb-FIX Cranial Stabilization System Skull Clamps do not directly contact the patient. The skull pins used with the skull clamp are the components which contact	Same. The Skull Pins are not included in K142238.

	the patient. The skull pins are included this 510(k).	
Type of head fixation	Three-point fixation	Three-point fixation
General Shape	"U" shape	Parallelogram
Clamping force	80 lbs	80 lbs
Interface for accessories	Yes	Yes
Imaging modality	Gold Standard and Premium Head Holding System • -None CT/MRI-compatible Head Holding System • CT- and MR-imaging	None
Sterility	Non-sterile	Non-sterile
Reprocessing	Automatic cleaning and disinfection between uses, steam sterilization possible	Manual or automatic cleaning and disinfection between uses
Materials	Gold Standard Head Holding System • Cast aluminum, stainless steel, gold plating Premium Head Holding System • Cast aluminum, stainless steel, gold plating, proprietary coating CT/MRI-compatible Head Holding System • PEEK, POM C	PEEK / Glass fiber composite Radel R (Polyphenylsulphone) Teflon, Hastelloy, stainless steel, silicone
Maquet Table Base Unit	Available for CT/MRI-compatible Head Holding System	No
Provides an interface for accessories like retractor systems, navigation adaptors or other items	Yes	Yes
	Subject Device	*Predicate Device*
Manufacturer	Medical Bees Gmbh	Integra LifeSciences Corporation
Product Name	mb-FIX Cranial Stabilization Systems Skull Pins	MAYFIELD Disposable and Reusable Titanium Skull Pins
Common Name	Skull Pin	Skull Pin
Classification Regulation	882.4460	882.4460
510(k) Number	K250423	K072208

Indications for Use	The mb-FIX Cranial Stabilization System Skull Clamps (Gold Standard Head Holding System, Premium Head Holding System and CT/MRI- compatible Head Holding System) are placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamps and pins are indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary. The CT/MRI-compatible model and the Titanium or PEEK + Titanium Skull Pins are used when intra-operative imaging is required. The mb-FIX Cranial Stabilization System provides an interface for accessories like retractor systems, navigation adaptors or other items.	The MAYFIELD Disposable and Reusable Titanium Skull Pins are intended for use with a MAYFIELD skull clamp that is placed on the patient's skull to hold their head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired and Intra-Operative MR imaging is used. The MAYFIELD Disposable and Reusable Titanium Skull Pins are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative MR imaging of the patient is used.
Design and Operating Principle	The mb-FIX Cranial Stabilization Systems Skull Pins are available in two sizes, Adult and Child. The pins are used with mb-FIX Cranial Stabilization Systems Skull Clamps to hold the patient's head and neck in a particular position during surgical procedures where rigid skeletal fixation is desired In preparation for surgery three Skull Pins are installed in a mb-FIX Cranial Stabilization Systems Skull Clamp. Two Skull Pins are inserted in the Rocker Arm side of the Clamp and a single Skull Pin is inserted on the opposite side.	Same – intended for use with MAYFIELD Skull Clamps
Recommended Age of Use	Two sizes, Adult and Pediatric The skull pin is not recommended for use on infants or children under 5 years of age.	Two sizes, Adult and Pediatric The skull pin is not recommended for use on infants or children under 5 years of age.
Material	• Titanium or stainless steel • PEEK + titanium • PEEK + stainless steel	Titanium
MR compatibility	• Pins manufactured from stainless steel, with or without PEEK – MR Unsafe • Pins manufactured from titanium, with or without PEEK – MR Conditional	MR Conditional
Reusability	Reusable	Reusable

Sterility	Non-sterile	Non-sterile
Reprocessing	Automatic cleaning and disinfection followed by steam sterilization	Reusable skull pins - Manual or automatic cleaning and disinfection followed by steam sterilization

Performance Testing:

Design verification and validation testing to support determination of substantial equivalence to the predicate consisted of the following tests:

- Mechanical testing in accordance with the requirements of standard ASTM F3395/F3395M-19 Standard Specification for Neurosurgical Head Holder Devices:
  - Skull clamp static load test
  - Skull clamp load loss
  - Skull clamp torque load resistance test
  - Skull clam vertical shear test
  - Skull clamp force delivery accuracy verification
- Skull pin shear testing to support mechanical integrity of the skull pins under loads occurring during surgical application.
- MRI evaluation and MRI compatibility testing in accordance with the requirements of standards ASTM F2052-21 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment; ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment; ASTM F2182-19e2 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance. Testing; ASTM F2119-24 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- Reprocessing validation testing of cleaning and sterilization instructions.
- Performance testing of the skull pins labeled “pediatric” to support the pediatric intended use.
- Performance testing to support the Zero Move skull clamp feature.

Acceptance criteria were met for all tests performed, demonstrating that the mb-FIX Cranial Stabilization Systems are substantially equivalent to the predicate devices and safe for their intended use.

Conclusion: The subject device mb-FIX Cranial Stabilization Systems has the same intended use and technological characteristics as the predicate devices. Based on the similarities of the indications for use, technological characteristics and design verification and validation test results, the mb-FIX Cranial Stabilization Systems are substantially equivalent to the predicate devices.