June 4, 2025

Medifield Medical Co., Ltd.
Bonggu Ha
Consultant
1st Floor, Building A, 94-40, Yongjeong-gyeongje-ro 1-gil,
Gunnae-myeon
Pocheon-si, Gyeonggi-do 11154
Korea, South

Re: K243368
Trade/Device Name: Montblanc Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: April 29, 2025
Received: April 29, 2025

Dear Bonggu Ha:

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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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.

Submission Number *(if known)*

K243368

Device Name

Montblanc Plate System

Indications for Use *(Describe)*

Montblanc Radius Plate System
The Montblanc Radius Plate System is intended for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius and distal ulna. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and malunions. This system can be used for palmar, dorsal or orthogonal application.

Montblanc Ankle Plate System
The Montblanc Ankle Plate System is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the distal tibia and fibula.

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) #: K243368

510(k) Summary

Prepared on: 2025-04-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medifield Medical Co., Ltd.
Applicant Address	1st Floor, Building A, 94-40, Yongjeong-gyeongje-ro 1-gil, Gunnae-myeon Pocheon-si Gyeonggi-do 11154 Korea, South
Applicant Contact Telephone	+82-70-8965-555
Applicant Contact	Mr. Bonggu Ha
Applicant Contact Email	bg.ha@kmcerti.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Montblanc Plate System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222267	Arthrex 2.4 mm Volar Distal Radius Plate System	HRS
K123241	Arthrex Fracture Plates	HRS
K151468	ARIX Wrist System	HRS
K193616	ARIX Ankle System	HRS
K170979	ARIX Ankle Fibula Hook Plate System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Montblanc Plate System consists of a series of plates and screws of varying lengths and orientations with Montblanc Radius Plate System and Montblanc Ankle Plate System. Each plate provides locking screw fixation. The proposed plates are manufactured from CP Grade 4 Titanium conforming to ASTM F67. The plates are sold as non-sterile, single-use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Montblanc Radius Plate System
The Montblanc Radius Plate System is intended for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius and distal ulna. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and malunions. This system can be used for palmar, dorsal or orthogonal application.

Montblanc Ankle Plate System
The Montblanc Ankle Plate System is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the distal tibia and fibula.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Montblanc Plate System is substantially equivalent to the predicate devices cleared under K222267, Arthrex 2.4 mm Volar Distal Radius Plate System and K123241, Arthrex Fracture Plates in which the basic design features, intended use, fundamental scientific technology, materials and sterility(non-sterile) are identical.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is substantially equivalent to the primary predicate device with respect to indication for use, product code, sterilization method, anatomical site of use, materials and standards to which the materials conform, hole dimension, locking mechanism, screw placement trajectory and compatible screw sizes and types. There's slight difference with the design between the subject device and predicate device, number holes, plate width range, plate length range and plate thickness range but these differences are slight and do not raise any risks in the safety and effectiveness of the subject device.
ARIX Wrist System (K151468), Arix Ankle System (K193616), ARIX Ankle Fibula Hook Plate System (K170979) were referred to the reference devices to support the appropriate scientific methods for the characterization of anodization coating (Type II, AMS 2487) on the subject device. Subject device has the identical anodization process compared to a previously cleared reference devices (K151468, K193616, K170979).
Therefore, we conclude that the different characteristics do not raise different questions of safety and effectiveness, and thus the subject device is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

General Tests were conducted as the Visual, Dimension and Mechanical Properties Test were conducted in accordance with characteristic of finished product to ensure indication for use. The performance test was implemented according to manufacturer SOP, FDA guidance Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway (Guidance for Industry and Food and Drug Administration Staff (Document issued on April 11, 2022.), ASTM F382, ASTM F543.
Plates with the smallest cross-sectional area of the critical region of the device were chosen as the worst-case sample for Minimum bending strength(N-m), Minimum bending structural stiffness
(N-m2). Screws with the smallest cross-sectional area of the critical region of the device and longest length were chosen as the worst-case sample for Torsional Strength Test (N-m), Driving Torque (insertion/removal torque testing)(N-m). Screws with the smallest cross-sectional area of the critical region of the device and shortest length were chosen as the worst-case sample for Axial Pullout Strength(N).

We believe that the performance test acceptance criteria is appropriate and that each test result ensure the effectiveness of Montblanc Plate System for the indications for use provided by the manufacturer and supports substantial equivalence.