April 2, 2026

Jeil Medical Corporation
Jinwoo Kim
RA Specialist
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Seoul, 08378
REPUBLIC OF KOREA

Re: K252246
Trade/Device Name: Leforte MMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: July 18, 2025
Received: March 3, 2026

Dear Jinwoo Kim:

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 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 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,

ANDREW I. STEEN -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
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Respiratory, ENT, and Dental Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252246

Device Name
Leforte MMF System

Indications for Use *(Describe)*
The Leforte MMF System is intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing.
The Leforte MMF System is indicated for the treatment of mandibular and maxillary fractures in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

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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510(k) Summary

[As required by 21 CFR 807.92]

510(k) #: K252246

1. Contact Details [21 CFR 807.92(a)(1)]

- Applicant Name: Jeil Medical Corporation
- Applicant Address: 702•703•704•705•706•707•804•805•807•812•815-ho, 55, Digital-ro 34-gil, Guro-gu, Seoul, 08378, Republic of Korea
- Applicant Contact Telephone: +82 2 850 3934
- Applicant Contact: Ms. Jinwoo Kim
- Applicant Contact Email: jinwookim@jeilmed.co.kr
- Date Prepared: April 2, 2026

2. Device Name [21 CFR 807.92(a)(2)]

- Device Trade Name: Leforte MMF System
- Common Name: Bone Plate
- Classification Name: Plate, Bone
- Regulation Number: 872.4760
- Product Code(s): JEY, DZL

3. Legally Marketed Predicate Devices [21 CFR 807.92(a)(3)]

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K122313	Stryker Universal SMARTLock Hybrid MMF System	JEY
K112457	LeForte System Bone Plate & Screw	JEY
K231887	ARIX Ankle Distal Tibia System	HRS

4. Device Description Summary [21 CFR 807.92(a)(4)]

	Model	Description	Materials	Product Code
MMF Plate	20L-MP-U13	Maxilla	Pure Titanium (ASTM F67)	JEY
	20L-MP-L13	Mandible		
Screw	20L-MS-0XX Series	Locking Screw	Titanium alloy (ASTM F136)	DZL
	20-MS-0XX Series	Non-locking Screw		
	20L-MS-FXX Series	MMF Screw		

The Leforte MMF System is intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing. The Leforte MMF System consists of plates and screws. Each plate is affixed to the maxilla and mandible using screws. Where clinically indicated, additional wiring may optionally be performed to enhance fixation between the plate and the dentition. The plates are then interconnected using wire or elastic materials looped around hooks on plates.

The Leforte MMF System plates are made of pure titanium in compliance with ASTM F67, while the screws are made of titanium alloy in compliance with ASTM F136. In accordance with these standards, both materials are recognized for their acceptable level of biological response following long-term clinical use.

The Leforte MMF System is supplied non-sterile. The devices must be sterilized prior to use in accordance with ISO 17665-1.

5. Intended Use/Indications for Use [21 CFR 807.92(a)(5)]

The Leforte MMF System is intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing.
The Leforte MMF System is indicated for the treatment of mandibular and maxillary fractures in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

6. Substantial Equivalence Comparison [21 CFR 807.92(a)(5), 21 CFR 807.92(a)(6), 21 CFR 807.92(b)(1)]

Parameter	Subject Device	Predicate Device	Remark
510(k) Number	K252246	K122313	-
Product Name	Leforte MMF System	Stryker Universal SMARTLock Hybrid MMF System	-
Manufacturer	Jeil Medical Corporation	Stryker	-
Product Code	JEY, DZL	JEY, DZL	Same
Indications for Use	The Leforte MMF System is intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing. The Leforte MMF System is indicated for the treatment of mandibular and maxillary fractures in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.	The Stryker Universal SMARTLock Hybrid MMF System is intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing. The Stryker Universal SMARTLock Hybrid MMF System is indicated for the treatment of mandibular and maxillary fractures in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.	Same
Human Factor	Bone anatomical shape	Bone anatomical shape	Same

Parameter		Subject Device	Predicate Device	Remark
Dimension	MMF Plate	1) Thickness: 0.8 mm 2) Length: 122.0, 114.8 mm 3) Number of screw holes: 13 ea 4) Number of hooks: 15 ea	1) Thickness: 0.5 mm 2) Length: 118.8, 101.2 mm 3) Number of screw holes: 9 ea 4) Number of hooks: 17 ea	Similar
	Screw	[Locking Screw] 1) Thread Diameter: Ø2.0 mm 2) Thread Length: 6, 8, 10, 12 mm 3) Type: Self-Drilling Screw	[Locking Screw] 1) Thread Diameter: Ø2.0 mm 2) Thread Length: 6, 8 mm 3) Type: Self-Drilling Screw	
		[Non-locking Screw] 1) Thread Diameter: Ø2.0 mm 2) Thread Length: 6, 8, 10, 12 mm 3) Type: Self-Drilling Screw	-	
		[MMF Screw] 1) Thread Diameter: Ø2.0 mm 2) Thread Length: 6, 8, 10, 12 mm 3) Type: Self-Drilling Screw	[MMF Screw] 1) Thread Diameter: Ø2.0 mm 2) Thread Length: 8, 12 mm 3) Type: Self-Drilling Screw	
Materials	MMF Plate	Pure Titanium (ASTM F67)	Pure Titanium (ASTM F67)	Same
	Screw	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	
Sterilization		Non-Sterile (User Steam Sterilization)	Non-Sterile (User Steam Sterilization)	Same
Biocompatibility		Biocompatible - MMF Plate: ASTM F67 - Screw: ASTM F136	Biocompatible - MMF Plate: ASTM F67 - Screw: ASTM F136	Same
Performance	MMF Plate	- Hook Strength Test - Tensile Test - 4-point Bending Test (ASTM F382) - 4-point Bending Fatigue Test (ASTM F382)	- Hook Strength Test - Tensile Test - 4-point Bending Test (ASTM F382) - 4-point Bending Fatigue Test (ASTM F382)	Similar
	Screw	- Torsion Test (ASTM F543) - Driving Test (ASTM F543) - Axial Pull-out Test (ASTM F543)	- Torsion Test (ASTM F543) - Driving Test (ASTM F543) - Axial Pull-out Test (ASTM F543)	
Substantial Equivalence Evidence		There are differences between the subject and predicate devices in design/shape, dimensions, and performance. For MMF plates, the subject and predicate MMF plates have similar overall shape, dimensions, and structural design. While there are minor differences in detailed product specifications, such as hole configuration and plate thickness, both devices incorporate screw holes designed to avoid dental roots and hooks intended for wire or elastic band fixation. The fundamental structural design and intended use of the devices are substantially equivalent. To evaluate the impact of these design differences on mechanical performance, comparative bench testing was performed. The subject device demonstrated mechanical performance that was comparable to that of the predicate device, and the subject device met all predefined acceptance criteria for performance testing. These results confirm that the observed differences in hole configuration and plate thickness do not adversely affect mechanical performance and do not raise new questions regarding the safety or effectiveness of the device. For screws, both the subject and predicate devices include locking screws and IMF screws. In addition, the subject device offers non-locking screws, which share the same intended function and bone engagement characteristics as the locking screws. Within the subject device, the locking and non-locking screws have identical thread diameters, thread lengths, and thread types. The primary difference between these screws lies in the screw head design, which is associated with the locking mechanism and does not affect the interaction between the screw threads and bone. The predicate device includes screws with the same thread diameter, similar thread lengths, and an identical intended use. Although the subject device provides a broader range of screw lengths, this difference does not affect the intended use or performance of		

Parameter	Subject Device	Predicate Device	Remark
	the screws and does not raise different questions of safety or effectiveness. To assess the impact of these differences, comparative screw performance testing was conducted in accordance with ASTM F543. Comparative testing confirmed that the subject device exhibits equivalent performance compared to the predicate device. Therefore, the differences in screw configuration, including the presence of non-locking screws and variations in screw head design, do not affect the safety or effectiveness of the device and do not impact substantial equivalence.		
Conclusion	There are no significant differences between the subject device and predicate device that would adversely affect the use of the product. It is substantially equivalent to predicate device in indications for use and technological characteristics.		

1) Indications for Use Comparison [21 CFR 807.92(a)(5)]
There are no differences of Indications for Use between the subject device and the predicate device (K122313).

2) Technological Comparison [21 CFR 807.92(a)(6)]
The subject and predicate devices have differences in design/shape, dimensions, and performance; however, these differences do not adversely affect the intended use of the product. The MMF plates of both devices have similar overall shape, dimensions, and structural design, and comparative bench testing demonstrated equivalent mechanical performance of the subject device. Both devices include locking screws and IMF screws, and the subject device additionally offers non-locking screws with the same intended function and bone engagement characteristics. Comparative screw performance testing conducted in accordance with ASTM F543 demonstrated that these differences do not affect performance. Therefore, the subject device has no significant technological differences that raise new questions of safety or effectiveness and is substantially equivalent to the predicate device.

7. Non-clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92(b)]

1) Reprocessing, Sterility, and Shelf-life
MMF Plates and Screws are single-use devices and supplied clean. It must be sterilized prior-to-use by end user. Sterilization validation was conducted in accordance with international standards ISO 17665-1, ISO 17665-2, with supporting test methods aligned with ISO 11138 and ISO 11737 series, and consistent with FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" to achieve a Sterility Assurance Level (SAL) of 10^{-6}. All test method acceptance criteria were met.

2) Biocompatibility
MMF Plates are made of Pure Titanium in compliance with ASTM F67 (Standard Specification for Unalloyed Titanium, for Surgical Implant Applications). In accordance with the standard, the material is recognized for their acceptable level of biological response following long-term clinical use. The MMF Plate in its final finished form is equivalent to the bone plate of the LeForte System Bone Plate & Bone Screw (K112457) (legally marketed device) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Screws are made of Titanium Alloy in compliance with ASTM F136 (Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications). In accordance with the standard, the material is recognized for their acceptable level of biological response following long-term clinical use. The Screw in its final finished form is equivalent to the bone screw of the ARIX Ankle Distal Tibia System (K231887) (legally marketed device) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

The biocompatibility of the Leforte MMF System has been demonstrated through documentation in accordance with FDA guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" by establishing the equivalence of the predicate devices to the final finished Leforte MMF System.

3) Performance Test

Bench tests were conducted for MMF plate and Screw to demonstrate substantial equivalence to the predicate device (K122313). The following performance tests were completed:

• MMF Plate
- Hook Strength Test
- Tensile Test
- 4-point Bending Test (ASTM F382)
- 4-point Bending Fatigue Test (ASTM F382)

** ASTM F382; Standard Specification and Test Method for Metallic Bone Plates*

• Screw
- Torsion Test (ASTM F543)
- Driving Test (ASTM F543)
- Axial Pull-out Test (ASTM F543)

** ASTM F543; Standard Specification and Test Methods for Metallic Medical Bone Screws*

Comparative testing confirmed that the subject device exhibits equivalent results compared to the predicate device with respect to hook strength testing and 4-point bending testing (including fatigue testing). In tensile testing, both the subject and predicate devices exceeded the defined acceptance criteria, demonstrating comparable resistance to clinically relevant tensile forces.

For screws, screw performance tests were conducted in accordance with ASTM F543. Comparative testing confirmed that the subject device exhibits equivalent results compared to the predicate device.

These results support that the subject device demonstrates substantially equivalent mechanical performance to the predicate device, with no indication of increased risk to safety or effectiveness.

4) Conclusion

The subject device and predicate device are intended to be used for temporary stabilization of mandibular and maxillary fractures in order to maintain proper occlusion during fracture healing. Both devices consist of MMF plates and screws. Although their specific designs and dimensions may differ, they are functionally equivalent.

Based on the indications for use, technological characteristics, bench testing, and comparison with the predicate device, the subject device has demonstrated substantial equivalence for its intended use.