Stryker Leibinger GmbH & Co. KG
Amelia Kesti
Staff Regulatory Affairs Specialist
Boetzinger Strasse 41
Freiburg, D-79111
GERMANY

July 12, 2024

Re: K240651
Trade/Device Name: MRI Universal
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: June 12, 2024
Received: June 12, 2024

Dear Amelia Kesti:

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.

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director

DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*

K240651

Device Name

MRI Universal

Indications for Use *(Describe)*

Universal CMF System

Intended use

The Universal CMF System is intended for stabilization and rigid fixation of the craniomaxillofacial (CMF) skeleton.

Indications for use

Craniomaxillofacial Implants

The Universal CMF System is Craniomaxillofacial (CMF) plate and screw system intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.

Mandible Implants

The Universal CMF System (mandible modules) is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction.

MP Lefort I Plates

Intended Use

The Stryker Leibinger Universal CMF and Universal 2.0 Mini Plating Systems are Craniomaxillofacial (CMF) plate and screw systems intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.

Indications for Use

The MP LeFort I Plates as part of the predicate subgroup Universal 2.0 Mini Plating System are implants indicated for osteotomy, stabilization, and rigid fixation of LeFort I fractures of the maxillofacial skeleton.

Stryker Upper-Face AXS Screws And Mid-Face AXS Screws

Indications for Use

The Stryker Universal CMF System is a Cranio-maxillofacial (CMF) plate and screw system intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.

Stryker MP, Mandible, HMMF And MMF AXS Screws

-Universal CMF System:

Intended Use

The Universal CMF System is intended for stabilization and rigid fixation of the craniomaxillofacial (CMF) skeleton.

Indications for Use

Craniomaxillofacial Implants

The Universal CMF System is Craniomaxillofacial (CMF) plate and screw system intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.

Mandible Implants
The Universal CMF System (mandible modules) is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction.

-Stryker Universal SMARTLock Hybrid MMF System:

Intended Use
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.

Indications for Use
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.

-Stryker MMF Screw

Intended use
The Stryker MMF Screw is intended for use as a bone screw in the temporary maxillomandibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.

Indications for use
The Stryker MMF Screw is intended for use as a bone screw in the temporary maxillomandibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.

Stryker Universal Orbital Floor System

Intended Use
The Stryker Universal Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit.

Indications for Use
The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.

Stryker Universal Smartlock Hybrid MMF System

Intended use
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.

Indications for use
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.

Stryker MMF Screw

Intended use

The Stryker MMF Screw is intended for use as a bone screw in the temporary maxillomandibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.

Indications for use

The Stryker MMF Screw is intended for use as a bone screw in the temporary maxillomandibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.

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.

510(k) Summary

This section provides a summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER [§807.92(a)(1)]

510(k) Owner: Stryker Leibinger GmbH & Co. KG
Boetzinger Strasse 41
D-79111 Freiburg, Germany

Submitter/ Contact Person: Amelia Kesti
Staff Regulatory Affairs Specialist
Stryker Craniomaxillofacial (CMF)
1941 Stryker Way
Portage, MI 49002

Phone: 269-330-5919

Date prepared: 07/11/2024

II. DEVICE [§807.92(a)(2)]

Trade Name:	MRI Universal
Abbreviated Name:	MRI Universal
Common or Usual Name:	Bone Plates, Intraosseous fixation screw or wire
Device:	MRI Universal
Classification Name & Regulation Description:	Plate, Bone; per 21 CFR §872.4760
Regulation Medical Specialty & Review Panel:	Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, Office of Product Evaluation and Quality (OHT1) / Division of Dental Devices (DHT1B)
Product Code:	Primary product code JEY, Secondary product code DZL
Regulatory Device Class:	Class II

*Note the company Stryker or legacy name Stryker Leibinger precedes the product/trade name and predicate device in some documentation.

III. PREDICATE DEVICE [§807.92(a)(3)]

A. Predicate Devices: The predicate devices for this Bundled, Traditional 510(k) are:

1. Primary Predicate: Universal CMF System – K221855
    i. Submission Branch of Predicate Device- Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health

2. Reference Predicate: MP LeFort I Plates – K171364
    i. Submission Branch of Predicate Device- Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health

3. Reference Predicate: Stryker Upper-Face AXS Screws and Mid-Face AXS Screws – K172572
    i. Submission Branch of Predicate Device- Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health

4. Reference Predicate: Stryker MP, Mandible, HMMF, and MMF AXS Screws – K231599
    i. Submission Branch of Predicate Device- Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health

5. Reference Predicate Device: Stryker Universal Orbital Floor System –K133461
    i. Submission Branch of Predicate Device- Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health

6. Reference Predicate Device: Howmedica and Howmedica Leibinger Bone Screw Washers – K980364
    i. Submission Branch of Predicate Device- Division of General and Restorative Devices, Office of Device Evaluation Center for Devices and Radiological Health.

7. Reference Predicate Device: Stryker Universal SMARTLock Hybrid MMF System – K122313
    i. Submission Branch of Predicate Device- Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health

8. Reference Predicate Device: Stryker MMF Screw – K050535

i. Submission Branch of Predicate Device- Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health

IV. DEVICE DESCRIPTION [§807.92(a)(4)]

A. Submission Branch of Subject Device: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, Office of Product Evaluation and Quality (OHT1) / Division of Dental Devices (DHT1B)

B. Subject Device: MRI Universal

This Bundled, Traditional 510(k) is for a single change the MR status that affects multiple devices and can be assessed during one review. There are no changes to the predicate devices themselves, just the addition to allow MR Conditional use of the implants in scope after MRI compatibility testing was completed. Associated labeling for each Predicate Device is also updated to reflect the MR conditional use of the implants.

V. INDICATIONS FOR USE [§807.92(a)(5)]

The proposed modifications do not alter the indications for use statement for the Subject Devices except for the Howmedica Leibinger Bone Washer. The washer individual indication is obsoleted and the washer is moved to the Universal CMF System under this submission. There is no change to any of the Indications for Use or Intended Uses for any of the other Predicate Devices. See Table 5-1 for the complete Indications for Use for each device.

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE

Aspect	Primary Predicate Device (K221855) Universal CMF System	Additional Predicate Device (K171364) MP LeFort Plates	Additional Predicate Device (K172572) Stryker Upper-Face AXS Screws and Mid-Face AXS Screws	Additional Predicate Device (K231599) Stryker MP, Mandible, HMMF and MMF AXS Screws	Additional Predicate Device (K133461) Stryker Universal Orbital Floor System	Additional Predicate Device (K980364) Howmedica and Howmedica Leibinger Bone Screw Washers	Additional Predicate Device (K122313) Stryker Universal SMARTLock Hybrid MMF System	Additional Predicate Device (K050535) Stryker MMF Screw
Intended Use	**Intended Use** The Universal CMF System is intended for stabilization and rigid fixation of the craniomaxillofacial (CMF) skeleton.	**Intended Use** The Stryker Leibinger Universal CMF and Universal 2.0 Mini Plating Systems are Craniomaxillofacial (CMF) plate and screw systems intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.	**Intended Use/Indications for Use** The Stryker Universal CMF System is a Cranio-maxillofacial (CMF) plate and screw system for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.	**Intended Use/Indications for Use** -Universal CMF System: The Universal CMF System is intended for stabilization and rigid fixation of the craniomaxillofacial (CMF) skeleton. -Stryker Universal SMARTLock Hybrid MMF System: 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. -Stryker MMF screw: The Stryker MMF Screw is intended for use as a bone screw in the temporary maxillomandibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.	**Intended Use** The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit.	**Intended Use/Indications for Use** The washers are intended to be used to provide additional surface area contact between the screw head and bone surface, when used in combination with bone screws for small bone reconstruction of the mandible, hand, foot, and the midfacial skeleton where there exists a condition of a thin cortex osteoporotic bone.*	**Intended Use** 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.	**Intended Use** The Stryker MMF Screw is intended for use as a bone screw in the temporary maxillomandibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.
Indications for Use Statement	**Indications for Use** Craniomaxillofacial Implants The Universal CMF System is a Craniomaxillofacial (CMF) plate and screw system intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction. Mandible Implants The Universal CMF System (mandible modules) is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction.	**Indications for Use** The MP LeFort I Plates as part of the predicate subgroup Universal 2.0 Mini Plating System are implants indicated for osteotomy stabilization and rigid fixation of LeFort I fractures of the maxillofacial skeleton.	**Indications for Use** The Stryker Universal CMF System is a Cranio-maxillofacial (CMF) plate and screw system for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction.	**Indications for Use** -Universal CMF System: Craniomaxillofacial Implants The Universal CMF System is Craniomaxillofacial (CMF) plate and screw system intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction. Mandible Implants The Universal CMF System (mandible modules) is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction. -Stryker Universal SMARTLock Hybrid MMF System: 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. -Stryker MMF screw: The Stryker MMF Screw is intended for use as a bone screw in the temporary maxillomandibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.	**Indication for Use** The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.	**Indications for Use** The washers are intended to be used to provide additional surface area contact between the screw head and bone surface, when used in combination with bone screws for small bone reconstruction of the mandible, hand, foot, and the midfacial skeleton where there exists a condition of a thin cortex osteoporotic bone.*	**Indications for use** 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.	**Indications for use** The Stryker MMF Screw is intended for use as a bone screw in the temporary maxilloman-dibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.

*The washers are only used in the mandible and are moving to the Universal CMF System under this submission

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [§807.92(a)(6)]

The subject device is compared to its predicate devices for substantial equivalence of technological characteristics based on the following criteria:

A. Principles of Operation
B. Technological Characteristics

A. Principles of Operation / Operating Principle

The basic operating principle of the Subject Device is identical to the basic operating principle of the Predicate Devices. There are no updates to the Predicate Devices themselves, only the allowance of the MR Conditional use of the plate and screw systems in the MR environment and associated labeling updates.

The fundamental scientific technology of the Subject Device has not changed. This is because the principle of operation, the mechanism of action, the intended use, and the materials of construction have not changed as a result of the MR conditional testing of the existing Predicate Devices.

B. Technological Characteristics

There are no updates to the Predicate Devices themselves, only the allowance of the MR Conditional use of the plate and screw systems in the MR environment and associated labeling updates. The technological characteristics remain the same as the corresponding Predicate Devices:

- Same operating principle
- Same mode of fixation
- Same area of contact and contact duration
- Same material

VII. PERFORMANCE DATA [§807.92(b)(1)]

There are no modifications to the subject devices as part of this submission, only the allowance of the MR Conditional use of the plate and screw systems in the MR environment and associated labeling updates.

Biocompatibility and sterility testing are not required as a basis for substantial equivalence. There is no change in the subject device material, manufacturing process, duration or location of contact, reprocessing methods, or testing standards followed relative to the Predicate Devices cleared in K221855, K171364, K172572, K231599, K133461, K980364, K122313, and K050535. The testing was performed following ISO 10993-1, DIN EN ISO 14937, DIN EN ISO 17665-1, and ISO/TS 17665-2.

Performance Bench Testing

Performance testing for displacement force, induced torque, and image artifacts were performed on reference devices that were identified as representative for all devices in scope of this submission. The testing was performed, and the labeling information was derived following ASTM F2503-23, ASTM F2213-17, ASTM F2052-21, and ASTM F2182-19.

A simulation study was performed covering all devices in scope of this submission to determine appropriate scanning times and wait times regarding RF induced heating. The simulation study was performed following ASTM F2182-19 and an additional Human Body Model simulation was conducted for the worst case construct.

All other mechanical performance testing of the devices in scope of this submission are not impacted by the changes in scope of this submission.

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing [§807.92(b)(2)]

Clinical testing was not required as a basis for substantial equivalence.

VIII. CONCLUSIONS [§807.92(b)(3)]

In summary, the subject device is substantially equivalent to its predicate device. The subject device's fundamental scientific technology, technological characteristics, and materials of construction are the same as the predicate devices. The subject device's intended use and indications for use have the same scope, content and meaning as the predicate devices. There are no new questions of safety or effectiveness. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence to the predicate devices.