



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

8/24/23

Re: K231599

Trade/Device Name: Stryker MP, Mandible, HMMF and MMF AXS Screws
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous fixation screw or wire
Regulatory Class: Class II
Product Code: DZL
Dated: June 1, 2023
Received: June 1, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Indications for Use

510(k) Number (if known)

K231599

Device Name

Stryker MP, Mandible, HMMF and MMF AXS Screws

Indications for Use (Describe)

-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.

-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 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.

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

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: 08/24/2023

II. DEVICE [§807.92(a)(2)]

Trade Name:	Stryker MP, Mandible, HMMF and MMF AXS Screws
Abbreviated Name:	Stryker MP, Mandible, HMMF and MMF AXS Screws
Common or Usual Name:	Bone Fixation Fasteners
Device:	Stryker MP, Mandible, HMMF and MMF AXS Screws
Classification Name & Regulation Description:	Intraosseous fixation screw or wire; per 21 CFR §872.4880
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:	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/Reference Devices: The Predicate/Reference Devices for this Bundled, Traditional 510(k) are:

1. Primary Predicate Device: Stryker 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
2. Reference Device: Universal CMF System – K221855
 - i. Submission Branch of Reference Device- Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health
3. Reference Device: Stryker MMF Screw – K050535
 - i. Submission Branch of Reference Device- Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health
4. Reference Device: Stryker Upper-Face AXS screws and Mid-Face AXS screws - K172572
 - i. Submission Branch of Reference 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: Stryker MP, Mandible, HMMF and MMF AXS Screws

The Subject Device screws are screw versions modified with the Stryker AXS Screw technology, where the abbreviation “AXS” stands for axial stability.

This submission is adding the AXS Screw technology to the Subject Device. The Subject Device screws have modified geometry and features which will be implemented as AXS Screws in each of the existing Predicate/Reference Device systems. This includes screws with a length range of 4-20 mm and a diameter range from 2.0-2.7 mm. The materials (titanium and stainless steel) are the same as for the corresponding Predicate/Reference Devices. There are no other changes to the Predicate/Reference Device systems, only the implementation of the AXS Screw technology to each existing product line. The Subject Device screws will have the same clinical application, treat the same craniomaxillofacial anatomical locations, and are for the same patient population as the corresponding Predicate/Reference Devices. There is no change to the indications for use or intended uses for the Predicate/Reference Devices.

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

The proposed modifications do not alter the indications for use statements for the Subject Device. The Subject Device indications for use are identical to the corresponding Predicate/Reference Devices.

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE

	Subject Device (K231599) Stryker MP, Mandible, HMMF and MMF AXS Screws	Primary Predicate Device (K122313) Stryker Universal SMARTLock Hybrid MMF System	Equivalence Discussion
Indications for Use Statement	<u>Stryker Universal SMARTLock Hybrid MMF System</u> 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. <u>Universal CMF System</u> 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. <u>Mandible Implants</u> 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. <u>Stryker MMF screw</u> 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.	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.	The Subject Device "Stryker MP, Mandible, HMMF and MMF AXS Screws" is comprised of three subsets of indications for use since this is a bundled 510(k). The indications for use of the Subject Device "Stryker Universal SMARTLock Hybrid MMF System" is identical to the indications for use of the Primary Predicate Device. For the Subject Device "Universal CMF System" and "Stryker MMF screw" the indications for use statements are identical to the indications for use of their corresponding Reference Devices. There are no changes in the indications for use to the corresponding Predicate/ Reference Devices. The intended uses remain unchanged.

*The use of the term "craniomaxillofacial" in the Subject Device's intended use and indication for use is to maintain alignment with the name of the System. Additionally, the term "craniomaxillofacial" is not intended for cranial use, but rather to address fractures to be

used for the orbital floor, mid-face, orthognathic, and mandible applications. This is considered a clarification and not a change based upon the prior K221855 clearance. For clinical conditions involving the cranium, Universal Neuro System (K031659) is utilized. This is a separate 510(k) cleared Device specifically intended for the cranium and is not part of this K231599 submission.

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

The Subject Device is compared to its Predicate/Reference 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 Stryker MP AXS Screws and Mandible AXS Screws, and the corresponding Reference Device MP Screws and Mandible Screws is to stabilize or rigidly fixate bone during osteotomy for fractures and reconstruction using plates and screws.

The basic operational principle of the Subject Device HMMF AXS Screws and MMF AXS Screws, and the corresponding Predicate/Reference Device HMMF Screws and MMF Screws is to temporarily stabilize the maxilla and mandible in the correct occlusal relationship. The functionality of the device remains the same from Predicate/Reference to Subject Device.

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 device modification.

The Subject Device screws consist of a threaded shaft for insertion and anchoring of the device into the bone. The Subject Device screw head interfaces with the corresponding AXS screwdriver blade to deliver the screw to the operating site and transmission of the rotational forces required for insertion. The mechanism of action of the modified Subject Device screws remains unchanged and is the same as the Predicate/Reference Device.

B. Technological Characteristics

Even with the modifications to the Subject Devices described in this Traditional 510(k), the technological characteristics remain the same as the corresponding Predicate/Reference Devices:

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

TABLE 6-1: TECHNOLOGICAL CHARACTERISTICS COMPARISON MATRIX OF SUBJECT DEVICE TO THE PREDICATE/REFERENCE DEVICES

Feature	Subject Device (K231599) Stryker MP, Mandible, HMMF and MMF AXS Screws	Primary Predicate Device (K122313) Stryker Universal SMARTLock Hybrid MMF System	Reference Device (K221855) Universal CMF System	Reference Device (K050535) Stryker MMF System	Reference Device (K172572) Stryker Upper-Face AXS Screws and Mid-Face AXS Screws	Explanation of Differences
Screw Head Design Modification	The Subject Device screw head modifications are changes to the cross-pin geometry, and a reduced head profile height. These modifications were performed to improve the screw to screwdriver blade interface, to provide improved pick-up performance, off-axis stability during insertion, and a lower profile height.	Predicate Device screw head design follows the cleared design in K122313.	Reference Device screw head design follows the cleared design in K221855.	Reference Device screw head design follows the cleared design in K050535.	Reference Device screw head design cleared in K172572. The AXS screw technology in the Subject Device of this submission is the same screw technology cleared in K172572.	Similar. The AXS screw technology in the Subject Device of this submission is the same screw technology cleared in K172572 Stryker Upper-Face AXS Screws and Mid-Face AXS screws. This submission applies this existing AXS technology to three existing Predicate/Reference Devices, creating the updated Subject Device. There are no other changes to the Predicate/Reference Device systems, only the implementation of the AXS screw technology in each existing product line.
Bone Thread and Locking Thread Geometry Modifications	<u>Stryker Universal SMARTLock Hybrid MMF System</u> No changes on screw thread design. It follows the cleared Predicate Device design in K122313. <u>Universal CMF System</u> The Subject Device screws except the Emergency screws have a bone thread modification that improves their insertion performance. Furthermore, the Mandible Locking Subject Device screws have a modification in their locking thread geometry. <u>Stryker MMF screw</u> No changes on screw thread design. It follows the cleared Reference Device design in K050535.	Predicate Device screw thread design follows the cleared design in K122313.	Reference Device screw thread design follows the cleared designs in K221855.	Reference Device screw thread design follows the cleared design in K050535.	Reference Device screw thread design cleared in K172572. The AXS screw technology in the Subject Device of this submission is the same screw technology cleared in K172572.	Similar. The AXS screw technology in the Subject Devices of this submission is the same screw technology cleared in K172572 Stryker Upper-Face AXS Screws and Mid-Face AXS screws. This submission applies this existing AXS technology to three existing Predicate/Reference Devices, creating the updated Subject Device. There are no other changes to the Predicate/Reference Device systems, only the implementation of the AXS screw technology in each existing product line.

Feature	Subject Device (K231599) Stryker MP, Mandible, HMMF and MMF AXS Screws	Primary Predicate Device (K122313) Stryker Universal SMARTLock Hybrid MMF System	Reference Device (K221855) Universal CMF System	Reference Device (K050535) Stryker MMF System	Reference Device (K172572) Stryker Upper-Face AXS Screws and Mid-Face AXS Screws	Explanation of Differences
Screw Diameter	<u>Stryker Universal SMARTLock Hybrid MMF System</u> 2.0 mm <u>Universal CMF System</u> <u>MP screws</u> 2.0-2.3 mm <u>Mandible screws</u> 2.0-2.7 mm <u>Stryker MMF screw</u> 2.0 mm	2.0 mm	<u>MP screws</u> 2.0 -2.3 mm <u>Mandible screws</u> 2.0 -2.7 mm	2.0 mm	1.2 – 1.9 mm	Same - The screw diameters of the Subject Device screws are the same as their corresponding Predicate/Reference Device screws.
Screw material	<u>Stryker Universal SMARTLock Hybrid MMF System</u> Titanium alloy (ASTM F 136) <u>Universal CMF System</u> Titanium alloy (ASTM F 136) <u>Stryker MMF screw</u> Implant Steel	Titanium alloy (ASTM F 136)	Titanium alloy (ASTM F 136)	Implant Steel	Titanium Alloy (ASTM F136)	Same - The screw materials of the Subject Device screws are the same as their corresponding Predicate/Reference Device screw materials.
Method of Sterilization	All provided non-sterile. Sterilized by end user using moist heat (steam) per applicable IFU parameters.	All provided non-sterile. Sterilized by end user using moist heat (steam) per applicable IFU parameters.	All provided non-sterile. Sterilized by end user using moist heat (steam) per applicable IFU parameters.	All provided non-sterile. Sterilized by end user using moist heat (steam) per applicable IFU parameters.	All provided non-sterile. Sterilized by end user using moist heat (steam) per applicable IFU parameters.	Same for all devices

VII. PERFORMANCE DATA [§807.92(b)(7)]

Based on the Risk Analysis performed on the modification to the Subject Device, Verification and Validation testing was performed in support of the substantial equivalence determination.

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, or reprocessing methods. Biocompatibility and sterility testing of the following Predicate/Reference Devices are leveraged.

Biocompatibility:

- Universal CMF System – K221855
- Stryker MMF Screw – K050535

Sterility:

- Stryker SMARTLock Hybrid MMF System - K122313
- Universal CMF System – K221855

Sterility testing following ISO 14937 and ISO 17665 as well as biocompatibility testing following ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-17, and ISO 10993-18 applies to the Subject Device.

Performance Bench Testing

As stated above, Verification and Validation (V&V) testing was performed on the Subject Device as dictated by the results of the Risk Analysis. A summary of the V&V testing results is included within the submission along with test reports:

- Pull-out Test per ASTM F543
- Full Insertion and Removal Test per ASTM F543
- Shaft Shear Test per ASTM F543
- Head Shear Test
- Locking Cantilever Bending Test
- Locking Torque to Failure Test
- Self-Retention Test

The Subject Device met all pre-defined acceptance criteria, and the results of the V&V tests support the substantial equivalence of the Subject Device to the Predicate/Reference Devices.

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)]

The results of the V&V tests data demonstrate that the Subject Device will perform as intended in the specified use conditions. 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 of the Subject Device to the Predicate/Reference Devices.