Stryker
Jonathan Schell
Staff Regulatory Affairs Specialist
750 Trade Centre Way - Suite 200
Portage, Michigan 49002

October 31, 2017

Re: K172572
Trade/Device Name: Stryker Upper-Face AXS screws and Mid-Face AXS screws
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: October 4, 2017
Received: October 5, 2017

Dear Jonathan Schell:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Stryker Upper-Face AXS screws and Mid-Face AXS screws

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5. 510(k) Summary K172572

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

I. SUBMITTER

510(k) Owner:	Stryker Leibinger GmbH& Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Jonathan Schell Staff Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-5596 Fax: 877-648-7114
Date prepared:	August 25, 2017

II. DEVICE

Trade Name:	Stryker Upper-Face AXS screws and Mid-Face AXS screws
Common or Usual name:	Bone Plating System
Classification name:	Bone Plate; 21 CFR §872.4760
Regulatory Class:	Class II
Product Code:	JEY

III. PREDICATE DEVICE

Predicate: Stryker Universal CMF System – K022185

IV. DEVICE DESCRIPTION

The predicate Universal CMF System, which was cleared in K022185, is intended for osteotomy, stabilization, and rigid fixation of CMF fractures and reconstruction. The Universal CMF System consists of an implant module for the respective anatomical and indicated areas with each containing various screw and plate versions and shapes. The Subject Device of this submission are the Upper-Face AXS screws and Mid-Face AXS (Subject Device) screws. This special 510(k) is submitted due to modifications made to the Subject Device. There have been no modifications to the plates, or meshes of the Predicate Device.

V. 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.

The proposed modifications do not alter the Indications for Use statement for the Subject Device. The Subject Device Indications for Use are identical to the Predicate Device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Subject Device is compared to the Predicate Device for substantial equivalence of technological characteristics based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The basic operational principle of the Subject Device remains the same as cleared with the Predicate Device: the operating principle for the System is to reconstruct, stabilize and/or provide rigid fixation in the craniomaxillofacial anatomy.

B. Technological Characteristics

Even with the modification to the Subject Device described in this special 510(k), the technological characteristics remain the same as the Predicate Device:

- Same operating principle,
- Same mode of fixation: plate fixation with screws,
- Same area of contact and contact duration: the screws have contact to tissue/bone with a duration greater than 30 days, and
- Same material.

VII. PERFORMANCE DATA

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.

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. 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 Device.

Animal Testing

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

Clinical Testing

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

VIII. CONCLUSIONS

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 Device.