Hager & Meisinger GmbH
Simon Goddeke
Official Correspondent
Hansemannstrasse 10
Neuss, 41468
GERMANY

October 08, 2021

Re: K201210
Trade/Device Name: Micro Screw System, Micro Screw System Basic
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: August 03, 2021
Received: September 10, 2021

Dear Simon Goddeke:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201210

Device Name
Micro Screw System, Micro Screw System Basic

Indications for Use *(Describe)*
The Micro Screw System, Micro Screw System Basic are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process in the oral cavity and maxillomandibular surgical field.

Note: Micro Screws are not intended to remain in the body permanently. After they have fulfilled their supportive function such as is the case after healing of a transplant, or healing of a fracture, for example, they need to be removed completely.

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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K201210 - 510(k) Traditional
Micro Screw System, Micro Screw System Basic

510(k) Summary

1. Applicant's Name and Address

Hager & Meisinger GmbH
Hansemannstraße 10
41468 Neuss, Germany
Phone: (0049) 2131 2012-292
Fax: (0049) 2131 2012- 223
Contact Person: Dr. Simon Göddeke
Regulatory Affairs
Date prepared: 10/07/2021

2. Device

Trade Name: Micro Screw System, Micro Screw System
Common Name: Basic Micro Screw System
Classification Name: Screw, Fixation, Intraosseous
Product Code: DZL
Regulation No: 872.4880
Class: II
Panel: Dental

3. Predicate Devices:

510(k) No.	Manufacturer	Trade Name	Material
K080430	STOMA	Bone Block Screw	Steel

K201210 - 510(k) Traditional
Micro Screw System, Micro Screw System Basic

510(k) Summary

4. Device Description:

The Micro Screw System, Micro Screw System Basic are used for the safe fixation and stabilisation of cortical bone grafts. These systems contain osteosynthesis screws made of surgical stainless steel with diameters of 1.0 mm and 1.2 mm.

This submission contains the following Screws:

Ref. No.	Description	Diameter [mm]	Length [mm]
39MSS10040	Micro Screw	1.0	4.0
39MSS10060	Micro Screw	1.0	6.0
39MSS10080	Micro Screw	1.0	8.0
39MSS10100	Micro Screw	1.0	10.0
39MSS10120	Micro Screw	1.0	12.0
39MSS10140	Micro Screw	1.0	14.0
39MSS12040	Micro Screw	1.2	4.0
39MSS12060	Micro Screw	1.2	6.0
39MSS12080	Micro Screw	1.2	8.0
39MSS12100	Micro Screw	1.2	10.0
39MSS12120	Micro Screw	1.2	12.0
39MSS12140	Micro Screw	1.2	14.0

5. Indications for Use:

The Micro Screw System, Micro Screw System Basic are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process in the oral cavity and maxillomandibular surgical field. Note: Micro Screws are not intended to remain in the body permanently. After they have fulfilled their supportive function such as is the case after healing of a transplant, or healing of a fracture, for example, they need to be removed completely.

6. Non-Clinical Bench Testing

The following standards have been followed for the development, production, performance and safety testing of Micro Screws:

- ASTM F138: Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
- ISO 5832-1: Implants for surgery — Metallic materials — Part 1: Wrought stainless steel

K201210 - 510(k) Traditional
Micro Screw System, Micro Screw System Basic

510(k) Summary

- AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ISO 17664: Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 17665-1: Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ASTM F543: Standard Specification and Test Methods for Metallic Medical Bone Screws
- ISO 14971: Medical devices — Application of risk management to medical devices
- ISO 15223-1: Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- ISO 10993-1: Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 7405: Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-5: Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

Several performance tests have been performed with the result that the design and function are equivalent to the predicted devices.

- Sterilization

  The sterilization validation was conducted according to ISO 17664, ISO 17665-1, ISO 11737-1 and -2, ANSI/AAMI ST79, ANSI/AAMI ST81, ISO 14937, ISO 11607-1 and DIN EN 868-2. The micro screws were successfully steam sterilized in 3 independent cycles following the reprocessing instructions of the test item´s manufacturer (using the half cycle procedure).

- Shelf-life

  The subject as well as predicate devices are delivered non-sterile.

- Biocompatibility

  The proposed device uses the same material and manufacturing methods as the predicate device and the intended use and the tissue contact are similar. Standards for material (ASTM F138) and biological safety (acc. to ISO 7405, ISO 10993-1, -5, ISO 14971) are met. The screws were shown to be non-cytotoxic in a cytotoxicity test. No claims to pyrogenicity are made. A chemical characterization following the cleaning process that includes these screws as well as products of comparable material (1.4197 stainless steel) showed that the screws

are safe in terms of auxiliary substances. Furthermore, concerns for physical complications regarding implantation are negligible as demonstrated by the long-term use of the predicate device that is comparable in construction and complexity. According to ISO 10993-1 (6.3.2.13) degradation aspects are also negligible, because the screws are not intended to be absorbed.

- Performance testing

  Several performance tests were conducted according to ASTM F543-17 to demonstrate SE:
  - A1: Torsional properties ("to measure the torsional yield strength, maximum torque, and breaking angle of the bone screw under standard conditions.")
  - A2: Driving torque ("to measure the torque required to drive a bone screw into a standard material.")
  - A3: Axial pullout strength ("to measure the axial tensile force required to fail or remove a bone screw from a defined material.")

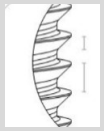
The Meisinger Micro Screws show higher insertion torques but also higher maximal torque compared to stoma bone screws. The final ratio of these two parameters is comparable between the screws (~9 vs. ~10). The breaking angle of the subject device was demonstrated to be equivalent to the predicate. However, the ductility of Meisinger Micro Screws is acceptable according to ASTM F543-17. The torques for insertion were demonstrated to be substantially equivalent between Meisinger Micro Screws and the predicate. The axial pullout strength showed comparable values for both analyzed screws.

7. Basis for substantial equivalence

The intended use and the technological characteristics are similar. The performance characteristics are also equivalent to the predicate device. Biocompatibility was demonstrated through a biocompatibility risk assessment and applicable testing in accordance with the requirements of ISO 10993-1. The subject as well as the predicate device can be sterilized with the same method. Based on this information we conclude that the Micro screws are substantially equivalent to the legally marketed predicate device.

K201210 - 510(k) Traditional
Micro Screw System, Micro Screw System Basic

510(k) Summary

Evaluation parameters	Manufacturer / 510(k) No.	Hager & Meisinger GmbH	Predicate device stoma® / K080430
Clinical properties	Indication	The Micro Screw System, Micro Screw System Basic are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process in the oral cavity and maxillomandibular surgical field. Note: Micro Screws are not intended to remain in the body permanently. After they have fulfilled their supportive function such as is the case after healing of a transplant, or healing of a fracture, for example, they need to be removed completely.	STOMA bone block screws are developed and manufactured to be used as non- active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process in the oral cavity and maxillomandibular surgical field. STOMA bone block screws are not intended to remain in the body permanently. After they have fulfilled their supportive function such as is the case after healing of a transplant, or healing of a fracture, for example, they need to be removed completely.
	Field of application	Oral, facial and maxillary surgery	Oral, facial and maxillary surgery
	Patient groups	Patients with the need of reconstruction after bone damage	Patients with the need of reconstruction after bone damage
	Clinical performance	-Bone fixation during duration of healing -No Osseointegration allowed, because device is removed after healing	-Bone fixation during duration of healing -No Osseointegration allowed, because device is removed after healing
Technical properties	Design	-Self-tapping thread -cylindrical shank -atraumatic apex 	-Self-tapping thread -cylindrical shank -atraumatic apex 
	Drill head geometry	Flat drill head with square bore 	Flat drill head with square bore 
	Outer-ø in mm	1,0 / 1,2	1,0 / 1,2 (Patent 0,7-1,6mm)
	Length in mm	4/6/8/10/12/14	4/6/8/10/12/14/16 (Patent 4-28mm)
	Material	Stainless steel (1.4441/UNS S 31673)	Stainless steel (Biodur 108; UNS S 29108)
	Operating conditions	-pilot hole drilled with native rotary instruments -Insertion and implantation with native screwdriver	-pilot hole drilled with native rotary instruments -Insertion and implantation with native screwdriver
	Technical specification	- smooth screw surface for simple removal	- smooth screw surface for simple removal

	Operating principle / critical performance standards	-friction with screwdriver -implantation by self-tapping thread -no osseointegration allowed -bone fixation as final purpose -safe removal (breakage safety intact drill bore)	-friction with screwdriver -implantation by self-tapping thread -no osseointegration allowed -bone fixation as final purpose -safe removal (breakage safety intact drill bore)
Biological properties	Used material as a function of patient contact	Stainless steel / long term surgically invasive contact with bone, mucosa and blood	Stainless steel / long term surgically invasive contact with bone, mucosa and blood
Literature	Sources	Internal developmental information	- Promotional material for stoma® micro screws [8] - Patent DE102009011461B4 retrospective clinical study

8. Conclusion

The subject device and the predicate device have equivalent intended use and technological characteristics and are made of equivalent materials. Both are austenitic stainless steels. The non-clinical bench testing did not reveal performance differences between the screws. Based on the assessment of applicable performance data, the subject device does not raise new performance or safety issues. Thus, we concluded that the subject device is substantially equivalent to the legally marketed predicate device listed above.