September 29, 2025

Hager & Meisinger GmbH
Wiebke Eckhardt
Head of Quality Management and Regulatory Affairs
Hansemannstr. 10
Neuss, 41468
GERMANY

Re: K250123
Trade/Device Name: Master-Pin X (MP Pin with thread) (36BMP000030 / MP30)
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: January 17, 2025
Received: August 29, 2025

Dear Wiebke Eckhardt:

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.

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,

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)*

K250123

Device Name

Master-Pin X (MP Pin with thread) (36BMP000030 / MP30)

Indications for Use *(Describe)*

The Master Pin X (MP Pins with thread) are indicated for the fixation of apical membrane ends at the local bone in order to avoid micromobility of the membrane. They allow the fixation of resorbable, non-resorbable and titanium-reinforced membranes in the dense cortical bone

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.

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

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510(k) #: K250123

510(k) Summary

Prepared on: 2025-09-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Hager & Meisinger GmbH
Applicant Address	Hansemannstr. 10 Neuss 41468 Germany
Applicant Contact Telephone	+4921312012388
Applicant Contact	Mrs. Wiebke Eckhardt
Applicant Contact Email	RA@meisinger.de

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Master-Pin X (MP Pin with thread) (36BMP000030 / MP30)
Common Name	Intraosseous fixation screw or wire
Classification Name	Screw, Fixation, Intraosseous
Regulation Number	872.4880
Product Code(s)	DZL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K093719	PRO-FIX PRECISION FIXATION SYSTEM MODEL PFM#, PFB#, PFT#	DZL

Device Description Summary

21 CFR 807.92(a)(4)

The Master-Pins X have been developed especially for the fixation of membranes. The pins are made of grade 5 titanium alloy and have a self-drilling thread that allows them to be inserted into the cortical bone. They have a total length of 3.2 mm and a declining thread diameter, with a maximum of 1.45 mm thread diameter.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Master Pin X (MP Pins with thread) are indicated for the fixation of apical membrane ends at the local bone in order to avoid micromobility of the membrane. They allow the fixation of resorbable, non-resorbable and titanium-reinforced membranes in the dense cortical bone

Indications for Use Comparison

21 CFR 807.92(a)(5)

There is a difference in the indications for use statement between the subject and the predicate device, consisting of the removal of the phrase specific to the fixation of bone grafts and bone grafting materials. The removal of this language does not affect substantial equivalence as it relates to the indications for use of the predicate device, as it is intended for the fixation, and support of barrier membranes.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device and the predicate devices have similar technological characteristics, and are made of similar materials. Their intended use does differ due to the removal in language specific to the fixation of bone grafts and bone grafting materials. The removal of this language does not affect substantial equivalence as it relates to the indications for use of the predicate device, as it is intended for the

fixation, fixation, and support of barrier membranes.
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 devices listed above.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance data were provided in support of the substantial equivalence determination:

A bench test using a modified version of ASTM F543 (insertion, pull-out, torque to failure, etc.) to account for device size was performed,. The results demonstrate equivalence betweeen the subject and predicate device. No concerns regarding performance or safety of the device have been raised.

Biocompatibility testing
A biocompatibility assessment on the subject device was performed per ISO 10993-1. Cytotoxicity testing was performed per ISO 10993-5. The results confirm the biological safety of the subject device.

Sterilization validation

Microbial efficiency control testing for steam sterilization (fractionated vacuum cycle, dynamic air-removal cycle and gravity-displacement cycle) according to the following standards were conducted: EN ISO 17664, EN ISO 17665-1, ANSI/AAMI ST79, ANSI/AAMI ST81, ANSI/AAMI TIR12, ASTM E 1766 mod, EN 556-1, ANSI/AAMI ST65
The results showed a sufficient spore log reduction (SLR >12), indicating successful validation of the parameters recommended in the reprocessing instructions for the subject device.

Clinical tests not applicable

Conclusion:
The subject device and the predicate devices have identical intended use and technological characteristics and are made of identical materials. No new risks are identified, thus we concluded that the subject device is substantially equivalent to the predicate device.