Hager & Meisinger GmbH
Melanie Otto
Regulatory Affairs Manager
Hansemannstr. 10
Neuss, 41468
GERMANY

October 17, 2024

Re: K240321
Trade/Device Name: MP Pin flat without thread
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: September 16, 2024
Received: September 16, 2024

Dear Melanie Otto:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240321

Device Name
MP Pin without thread, flat head

Indications for Use *(Describe)*
The MP Pins without thread, flat head are indicated for the fixation of apical membrane ends at the local bone in order to avoid micromobility of the membrane. They allow for the fixation of resorbable and non-resorbable membranes.

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) Traditional
K240321 - MP Pin without thread, flat head
510(k) summary

Contact Details

Applicant Name	Hager & Meisinger GmbH
Applicant Address	Hansemannstr. 10 Neuss 41468 Germany
Applicant Contact Telephone	+492132012206
Applicant Contact	Ms. Melanie Otto
Applicant Contact Email	RA@meisinger.de
Date prepared	10/17/2024

Device Name

Device Trade Name	MP Pin without thread, flat head
Common Name	Intraosseous fixation screw or wire
Classification Name	Screw, Fixation, Intraosseous
Regulation Number	872.4880
Product Code(s)	DZL

Primary Predicate Device

Predicate # Predicate	K130682
Trade Name Product	Meisinger MEITAC, Meisinger Master-Pin-Control
Code	DZL

Device Description Summary

Pin with a flat head for the fixation of resorbable and non-resorbable membranes.

Intended Use/Indications for Use

The MP Pins without thread, flat head are indicated for the fixation of apical membrane ends at the local bone in order to avoid micromobility of the membrane. They allow for the fixation of resorbable and non-resorbable membranes.

Indications for Use Comparison

The indications for use of the subject device "MP Pin without thread, flat head" are identical to the indications for use of the predicate device "Meisinger MEITAC, Meisinger Master-Pin-Control".

Technological Comparison

The subject device and predicate devices are composed of the same titanium alloy (3.7165 6Al-4V ELI) and have identical principles of operation (i.e., the fixation of resorbable and non-resorbable membranes). There are differences in device

dimension due to the difference in pin head geometry (subject device has a flat head vs. hexagonal connection of the predicate device) which does not raise new risks with regard to safety or performance, as determined by internal validation based on the FDA-recognized standard IEC 62366-1).

Performance Data

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

-Biocompatibility testing: Cytotoxicity testing was performed per ISO 10993-5. The results confirm the biological safety of the subject device.

-Sterilization validation was performed per ISO 17664 and ISO 17665-1

Conclusions

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.