June 27, 2025

Ustomed Instrumente Ulrich Storz GmbH & Co. KG
℅ Angelika Scherp
Regulatory Affairs Consultant
Business Support International
Aalsmeerweg 123-3
Amsterdam, 1059AH
Netherlands

Re: K243190
Trade/Device Name: USTOMED Bone Fixation/Bone Augmentation Systems - PIN
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: September 28, 2024
Received: May 27, 2025

Dear Angelika Scherp:

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)*
K243190

Device Name
USTOMED Bone Fixation/Bone Augmentation Systems – PIN

Indications for Use *(Describe)*
USTOMED Bone Fixation/Bone Augmentation Systems – PIN is intended for fastening membranes during bone regenerative treatment.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Date:	June 26, 2025	
Submitter:	Name:	USTOMED Instrumente – Ulrich Storz GmbH & Co. KG
	Address:	Bischof-Sproll-Strasse 2 D-78532 Tuttlingen Germany
	Contact Person:	Oliver Keuffel
	Telephone:	+49.7461.965850
Product:	Name of Device:	USTOMED Bone Fixation/Bone Augmentation Systems - PIN
	Common Name:	Pin
	Product Codes:	DZL Intraosseous Fixation Screw or Wire, Reg. #872.4880
	Regulatory Class:	II
Predicate Device:	K201561 Membrane Tack	
Device Description:	USTOMED Bone Fixation/Bone Augmentation Systems – PIN consists of a titanium pin. The Pin can be used to fasten third-party non-absorbable PTFE and titanium-reinforced membranes up to a thickness of 1.0mm cleared by FDA for stabilization and support of bone grafts in dento-alveolar bony defect sites (product code JEY). After fulfilling its supportive function, which is typically achieved within three to nine months, the Pin must be removed, as it is not intended to remain in the body permanently. The Pin are intended for single use and provided non-sterile for cleaning and sterilization by the user before use.	
Indications for Use:	USTOMED Bone Fixation/Bone Augmentation Systems – PIN is intended for fastening membranes during bone regenerative treatment.	
Technological Characteristics:	Subject and predicate device technological and performance characteristics of are the same or similar, as shown by the following table.	

Manufacturer	**USTOMED GmbH & Co. KG**	**NEOSS Ltd.**	--
K-Number	**K243190**	**K201561**	--
Device	**Pin**	**Membrane Tacks and Screws**	--
Intended Use	Pins are intended for fastening membranes during bone regenerative treatment.	Membrane Tacks and Membrane Screws are intended for fastening membranes during bone regenerative treatment. These membrane fastening means are in direct body contact, intended for temporary use only. Membrane fastening means are submerged and clinically implanted more than 30 days with an expected	Subject device and predicate Membrane Tack intended uses are identical.

		duration of implantation of three to nine months, or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used.	
Product Code	DZL Intraosseous fixation screw	DZL Intraosseous fixation screw	Same
Material	Grade 5 Titanium Alloy	Grade 5 Titanium Alloy	Same
Dimensions	Head diameter: 2.5 mm Length: 3 mm	Head diameter: 2.5 mm Length: 3 mm	Same
Patient Contact	Tissue and bone	Tissue and bone	Same
Duration of use	> 30 days, expected 3-9 months or until bone regeneration is complete	> 30 days, expected 3-9 months or until bone regeneration is complete	Same
Sterility	Non-sterile	Ref. K168750 – Non-sterile	Same
Reusability	No – single use	No – single use	Same
Decontamination Method	Steam sterilization by user	Ref. K168750 – steam sterilization by user	Same

Performance Testing: Design verification and validation testing to support determination of substantial equivalence consisted of the following tests:

- Dimensional verification of specifications.
- Validation testing of the recommended end user device reprocessing procedures
- Mechanical testing in accordance with the requirements of ASTM F543-17
- Evaluation of biocompatibility in accordance with ISO 10993-1
- Cytotoxicity in accordance with ISO 10993-5
- Materials chemical analysis in accordance with ISO 10993-18

Acceptance criteria were met for all tests performed.

Conclusion: By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. The subject device USTOMED Bone Fixation/Bone Augmentation Systems – PIN has the same intended use and the same technological characteristics as the predicate device. The information provided above indicates that USTOMED Bone Fixation/Bone Augmentation Systems – PIN is substantially equivalent to the predicate device.