July 31, 2026

W&H Dentalwerk Bürmoos GmbH
Gerhard Weidler
Regulatory Affairs Manager
Werner-Bader-Straße 1
Bürmoos, Salzburg 5111
AUSTRIA

Re: K253655
Trade/Device Name: Angled Screwdriver MED (M-SD090)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZI, DZJ
Dated: June 23, 2026
Received: June 23, 2026

Dear Gerhard Weidler:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
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Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253655

Please provide the device trade name(s).

Angled Screwdriver MED (Type: M-SD090)

Please provide your Indications for Use below.

The surgical transmission instrument is indicated for:
Drilling and screwing of osteosynthesis screws, implants and plate systems into organic hard tissue in oral/ maxillofacial surgery.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253655

510(k) Summary

Prepared on: 2026-07-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	W&H Dentalwerk Bürmoos GmbH
Applicant Address	Werner-Bader-Straße 1 Bürmoos Salzburg 5111 Austria
Applicant Contact Telephone	+4362746236102
Applicant Contact	Dr. Gerhard Weidler
Applicant Contact Email	gerhard.weidler@wh.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Angled Screwdriver MED (M-SD090)
Common Name	Bone cutting instrument and accessories
Classification Name	Drill, Bone, Powered
Regulation Number	872.4120
Product Code(s)	DZI, DZJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K082649	Synthes Screwdriver 90°	DZI
K213221	WS-75 handpiece of "AMADEO, M-UK1015 (incl. attachments and accessories)" submission	ERL

Device Description Summary

21 CFR 807.92(a)(4)

W&H's Angled Screwdriver (M-SD090) is suitable for drilling holes and screwing of osteosynthesis screws, implants and plate systems in organic hard tissue in the field of maxillofacial surgery. Screwing can be performed manually with a hand drive or mechanically with a motor drive.
The angled screwdriver enables safe drilling with any drive motor with an ISO 3964 coupling, thanks to an integrated automatic gearbox that increases the torque of the motor (which the respective motor delivers at a speed of 20,000 rpm) by a factor of 6.5. The gearbox is only active during drilling when a motor with ISO 3964 coupling (or shorter couplings) is connected to the angled screwdriver.
The new angled screwdriver can be exclusively used for mechanical screwing-in in combination with W&H's AMADEO (K213221) device. Here, a torque limiter on the control unit ensures precise and torque-accurate screwing in of the bone screws.
The WS-75 handpiece (K213221) of the AMADEO device is used as a reference device within this submission.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The surgical transmission instrument is indicated for:
Drilling and screwing of osteosynthesis screws, implants and plate systems into organic hard tissue in oral/maxillofacial surgery.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use statements of the new M-SD090 and the predicate device are identical.

Both devices can be used manually (main application) or powered via a surgical unit and are indicated for the insertion (which includes pre-drilling, drilling and screwing) of osteosynthesis (bone fixation) screws in maxillofacial surgery.
The reference device, WS-75, is also intended to be used for the insertion (which includes pre-drilling, drilling and screwing) of osteosynthesis (bone fixation) screws in maxillofacial surgery.

Technological Comparison

21 CFR 807.92(a)(6)

Both devices, the M-SD090 and the predicate device, share the same technological characteristics, like the basic functions (manual or mechanical use), the design, the ISO 3964 coupling, as well as the reprocessing instructions.
The reference device, the WS-75 handpiece, has a similar basic functionality, it supports drilling and the placement of implant screws in dental and maxillofacial surgery, can be connected via an ISO 3964 coupling, has the same reprocessing instructions and shares a similar design concept.

The new device and the predicate device share a similar maximum input speed (M-SD090 - 20.000 rpm vs. predicate device - 15.000 rpm) as well as the standard gear ratio (M-SD090 - 1.6:1 vs. predicate device 2:1).
The differing maximum drill speed of the new device with 3,056 rpm (predicate 7,500 rpm) is based on the drill manufacturer's specifications. The W&H defined drive speed is 20,000 rpm and results in a drill speed of 3,056 rpm due to the reduction ratio of 6.5:1 (head reduction ratio 1.6:1 and automatic planetary gear reduction ratio 4:1) which allows the new device also to be used with less powered drive units.
The differences of the WS-75 handpiece compared to the M-SD090 device are in the design (shorter neck, no manual use, no 90° head angle) and in technological parameters (gear ratio, max. input speed).
The new screwdriver is specifically designed to enable drilling and screw insertion in anatomically restricted treatment areas, improving access while maintaining established safety and performance characteristics. The basic technological characteristics of the WS-75 are retained in the M-SD090.
The WS-75 handpiece, cleared under K213221, provides appropriate technical context to support the evaluation of the subject device's technological characteristics. The similarities in intended use, functional principles, materials, and reprocessing methods demonstrate that the identified differences do not affect safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Nonclinical testing to support submission:
To verify the performance requirements of the proposed device, the following tests were performed in accordance with standards and FDA guidance documents. All tests were completed successfully.

Mechanical and thermal Safety testing according to ISO 14457 "Dentistry — Handpieces and motors" was performed and shows that the new device is in compliance with this standard.

A biocompatibility evaluation of patient contacting components of the proposed device according to the requirements ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", ISO 10993-5 "Biological evaluation of medical devices Part 5: Test for cytotoxicity", ISO 10993-10 "Biological evaluation of medical devices - Part 10: Tests for skin sensitization", ISO 10993-18 "Biological evaluation of medical devices – Part 18: Chemical characterization of materials", ISO 10993-23 "Biological evaluation of medical devices – Part 23: Tests for irritation" and ISO 7405 "Dentistry - Evaluation of biocompatibility of medical devices used in dentistry" was conducted.

Reprocessing validation (Cleaning, Sterilization) according to FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" was performed.

Clinical Testing:
No clinical testing was required to support this submission.

Conclusions drawn from conducted performance tests:
Results of performance testing demonstrate that the functionality, integrity, as well as safety and effectiveness of the new device, W&H's Angled Screwdriver MED (M-SD090), is sufficient for its intended use. Verification test results demonstrate that the subject device is substantially equivalent to the predicate device.