July 18, 2024

Guangdong Jinme Medical Technology Co., Ltd.
℅ Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District, Guangzhou
Guangdong,
CHINA

Re: K240340
Trade/Device Name: Surgical Drive System (Model: ES70, ES90, E8)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZI, ERL
Dated: February 5, 2024
Received: February 5, 2024

Dear Cassie Lee:

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.

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
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)*

K240340

Device Name

Surgical Drive System (Model: ES70, ES90, E8)

Indications for Use *(Describe)*

The Surgical Drive System (Model: ES70, ES90, E8) is indicated for: drilling, milling, cutting, sawing, screwing (for positioning) of osteosynthesis screws, implants and plate systems in soft and hard tissue.
Including: ENT surgery and Maxillofacial surgery

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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510(k) Summary of K240340

1. Date of the summary prepared: July 17, 2024

2. Submitter's Information

Company Name: GUANGDONG JINME MEDICAL TECHNOLOGY CO., LTD.
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Application Correspondent

Contact Person: Ms. Cassie Lee
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Title: Manager
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

3. Subject Device Information

Company Name: GUANGDONG JINME MEDICAL TECHNOLOGY CO., LTD.
Trade/Device Name: Surgical Drive System (Model: ES70, ES90, E8)
Common Name: Drill, Surgical, Ent (Electric Or Pneumatic) Including Handpiece
Classification Name: Ear, nose, and throat electric or pneumatic surgical drill.
Product Code: ERL, DZI
Regulation Number: 21 CFR 874.4250, 21 CFR 874.4360
Review Panel: Ear Nose & Throat
Regulatory Class: II

4. Predicate Device Information

510(k) Number: K213221
Company Name: W&H Dentalwerk Bürmoos GmbH
Trade/Device Name: AMADEO, M-UK1015 (incl. attachments and accessories)
Common Name: Drill, Surgical, Ent (Electric Or Pneumatic) Including Handpiece
Classification Name: Ear, Nose, and Throat Electric or Pneumatic Surgical Drill
Product Code: ERL, DZI
Regulation Number: 21 CFR 874.4250
Regulatory Class: II

5. Device Description

The Surgical Drive System is an electrical drive unit, including a motor, power console, foot control, connection cables, and other accessories. It is intended for use in surgical procedures involving incision/cutting, removal, drilling, and sawing of soft and hard tissue and bone.

The basic function of the Surgical Drive System is the conversion of electrical energy into a mechanical rotary motion. The control unit is used to control the connected motor and the integrated pump. The integrated touch display is used to monitor the actual settings and to change, within predetermined limits, the operating parameters. The foot control is used for activation/deactivation of the motor and changing parameters e.g. program, pump state, and motor direction. The motor's function is to provide power for handpieces with the gear ratio (1:1, 1:4.2, 1:5, 3.2:1, 3.4:1, 40:1), the Max. speed of the motor is 40000 min-1, and it is designed with an ISO 3964 Type 3 connector.

6. Intended Use / Indications for Use

The Surgical Drive System (Model: ES70, ES90, E8) is indicated for: drilling, milling, cutting, sawing, screwing (for positioning) of osteosynthesis screws, implants and plate systems in soft and hard tissue. Including: ENT surgery and Maxillofacial surgery

7. Comparison to predicate devices

Compare with the predicate devices, the subject device is very similar in technical design, intended use/indications for use, functions, etc. And the differences between the subject device and predicate devices do not affect substantial equivalence. Please refer to the detailed Substantial Equivalence Comparison of the subject device and predicate devices in the following table.

Elements of Comparison	Subject Device	Predicate Device 1 (Primary Predicate device)	Remark
Company	GUANGDONG JINME MEDICAL TECHNOLOGY CO., LTD.	W&H Dentalwerk Bürmoos GmbH	--
Device Name	Surgical Drive System (Model: ES70, ES90, E8)	AMADEO, M-UK1015 (incl. attachments and accessories)	--
510(k) Number	K240340	K213221	--
Regulation Number	21 CFR 874.4360, 21 CFR 874.4250	21 CFR 874.4360, 21 CFR 874.4250	Same
Product Code	ERL, DZI	ERL, DZI	Same
Class	II	II	Same
Intended Use / Indications for Use	The Surgical Drive System (Model: ES70, ES90, E8) is indicated for: drilling, milling, cutting, sawing, screwing (for positioning)	The drive unit for surgical transmission instruments is indicated for: drilling, milling, cutting, sawing, screwing (for positioning) of	Same

	of osteosynthesis screws, implants and plate systems in soft and hard tissue. Including: ENT surgery and Maxillofacial surgery	osteosynthesis screws, implants and plate systems in soft and hard tissue. Including: ENT surgery and Maxillofacial surgery	
Sterility	Provided non-sterile	Provided non-sterile	Same
Use	Rx only	Rx only	Same
Mains voltage Frequency	110~220Va.c., 50Hz/60Hz	120 V, 50-60 Hz	Similar Note 1
Operating Mode	Intermittent duty S3 (load time max. 3min / rest time min. 10min)	Intermittent duty S3 (load time max. 3min / rest time min. 5min)	Similar Note 2
Foot control	Wired	- Wireless - Wired	Similar Note 3
Components	- Control Unit - Motor (with the cable) - Foot control - Power cord - Pipeline head - Power fuse - Instruction for use	- Control Unit - Motor - Handpiece (in different versions) - Foot control (in different versions) - Power cord - Instruction for use	Similar Note 4
Motor coupling systems classification (ISO 3964)	Type 3	No publicly available	Similar Note 5

Comparison in Detail(s):

Note 1: Although the " Mains voltage Frequency" of the subject device is slightly different from the predicate devices, both the subject device and the predicate devices conducted the safety test according to the IEC 60601 series standards, and it meets the power supply requirements of the US, and the test results are in compliance with safety standards' requirements. So, the difference between the subject and predicate devices will not affect substantial equivalence.

Note 2: Although the "Operating Mode" of the subject device is slightly different from the predicate devices, both the subject device and predicate device K213221 are designed in the operating mode as Intermittent duty S3 and the max. load time is the same and the min rest time is similar. The Rest time will not affect the treatment. The Rest time only affect the temperature raise and both the subject device and predicate devices conducted the IEC safety test, and the test results are in compliance with safety standards' requirements. So, the difference between the subject and predicate devices will not affect substantial equivalence.

Note 3: Although the "Foot control" designed with wire of the subject device is slightly different from the predicate devices, the predicate device K213221 has both wired and wireless Foot control. So, the difference between the subject and predicate devices will not affect substantial equivalence.

Note 4: Although the "Components" of the subject device are slightly different from the predicate devices because they will provide different accessories or attachments. But all of them will provide the main components such as Control Unit, Motor, Foot control, Power cord, and Instruction for use. So, the difference between the subject and predicate devices will not affect substantial equivalence equivalence.

Note 5: Although the "Motor coupling systems classification (ISO 3964)" of the predicate device is not published our subject device designed the coupling systems classification (ISO 3964) as Type 3. Exactly, both the subject device and predicate device should be designed with proper specifications per ISO 3964 or an equivalent method. Furthermore, we also conducted the IEC series standards with a connected handpiece, the test results show that the subject device's performance can meet the standards' requirements without any accidentally disconnected. So, we can believe this difference between the subject and predicate devices will not affect substantial equivalence.

8. Test Summary

8.1 Summary of Non-clinical tests

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- Electrical safety test according to IEC 60601-1 and IEC 8060-2-60 standard;
- Electromagnetic compatibility test according to IEC 60601-1-2 and IEC/TR 60061-4-2 standard;
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling;
- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile;
- Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices;
- Software verification and validation test according to the requirements of IEC 62304 and the FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.
- Validation of the effectiveness of reprocessing and validation of the maximum number of reprocessing according to ISO 17665-1;

8.2 Summary of Clinical Testing

Clinical testing is not required for this submission. The non-clinical performance testing described above is sufficient to support substantial equivalence of the subject device to the predicate.

9. Final conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is substantially equivalent to the legally marketed predicate device K213221.