Top-Rank Health Care Co., Ltd.
% Owen He
Consultant
Microkn Medical Technology Service (Shanghai) Co., Ltd.
Rm. 901, Huafa Center, 889 Pinglu Rd., Jing 'An District, Shanghai
Shanghai, Shanghai 200040
China

October 30, 2026

Re: K260575
Trade/Device Name: AutoGel Pad (400-046,400-005)
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: MUI
Dated: September 30, 2026
Received: September 30, 2026

Dear Owen He:

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.
Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81.

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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Digitally signed by Michael D. O'hara -S
Date: 2026.10.30 08:47:32 -04'00'

For
Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.	K260575

Please provide the device trade name(s).

AutoGel Pad (400-046,400-005)

Please provide your Indications for Use below.

The AutoGel Pad is a conductive medium for transmission of therapeutic ultrasound to tissue. The device can be used for ultrasound physical therapy through generation of deep heat in soft tissues for adults in professional medical institutions, suitable for intact skin on the body surface.

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

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

510(k) #: K260575

510(k) Summary

Prepared on: 2026-10-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Top-Rank Health Care Co., Ltd
Applicant Address	Mashan Village, Dongguan Street, Shangyu District, Shaoxing City, Zhejiang Province (Zip Code 312352) Shaoxing Zhejiang 312352 China
Applicant Contact Telephone	+86 15397071887
Applicant Contact	Mr. Deniss Wen
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Correspondent Name	Microkn Medical Technology Service (Shanghai) Co.,Ltd.
Correspondent Address	Room 901, Huafa Center, 889 Pinglu Road, Jing 'an District, Shanghai Shanghai Shanghai 200040 China
Correspondent Contact Telephone	+86 18136188802
Correspondent Contact	Mr. Owen He
Correspondent Contact Email	fda@microkn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AutoGel Pad (400-046,400-005)
Common Name	Diagnostic ultrasonic transducer
Classification Name	Media, Coupling, Ultrasound
Regulation Number	892.1570
Product Code(s)	MUI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K031018	AutoGel Pad	MUI

Device Description Summary

21 CFR 807.92(a)(4)

AutoGel Pad is composed of carrageenan, glycerol, preservative, purified water, etc. It is usually an integral type of water-based polymer gel, The product is provided in a non-sterile form.
In the ultrasonic treatment operation, the device is placed between the skin and the radiation surface of the treatment head. The device fills the gap between the contact surface, eliminates the air in the gap, and reduces the acoustic impedance difference between the probe and the skin, thus reducing the loss of ultrasonic energy.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The AutoGel Pad is a conductive medium for transmission of therapeutic ultrasound to tissue. The device can be used for ultrasound physical therapy through generation of deep heat in soft tissues for adults in professional medical institutions, suitable for intact skin on the body surface.

Indications for Use Comparison

21 CFR 807.92(a)(5)

● Indications for use for the AutoGel Pad(subject device):
The AutoGel Pad is a conductive medium for transmission of therapeutic ultrasound to tissue. The device can be used for ultrasound physical therapy through generation of deep heat in soft tissues for adults in professional medical institutions, suitable for intact skin on the body surface.
● Indications for use for the predicate device AutoGel Pad (K031018):
Conductive medium for transmission of therapeutic ultrasound to tissue.

Both devices share the core intended use as a conductive medium for transmission of therapeutic ultrasound to tissue.
While the subject device's indications contain supplementary contextual details including treatment mechanism,target patient population,use environment and application condition,these supplementary items are descriptive clarifications of the core function rather than new, distinct intended uses.

These additional descriptive elements introduce no new clinical indications, off-scope patient populations, operating modes, or safety risks beyond the predicate. The subject device stays within the predicate's safe and effective clinical range, adds no new clinical hazards, and does not affect substantial equivalence.

Technological Comparison

21 CFR 807.92(a)(6)

The Proposed Device (AutoGel Pad, Model 400-046, 400-005) and the legally marketed Predicate Device (AutoGel Pad, 510(k) No. K031018) are both Class II therapeutic ultrasound conductive gel pad devices, sharing Product Code MUI and falling under regulatory classification 21 CFR 892.1570. Both devices are indicated for use as a conductive medium for transmission of therapeutic ultrasound to tissue, with contact to intact skin surface, non-sterile supply, single-use design, and intended to be used as an accessory for "AutoSound" equipment.

All patient contact materials of the Proposed Device comply with the requirements of ISO 10993 series standards, and the device has passed complete performance verification, shelf-life validation, and simulated transportation testing.

The parameter range fully covers the clinically safe and effective treatment range of the predicate device, without introducing any new clinical risks, having no negative impact on the safety and effectiveness of the device in clinical application, and not affecting the establishment of substantial equivalence between the two devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical TestingNon-clinical tests were conducted to verify that the Proposed Device meets all design specifications and is Substantially Equivalent (SE) to the Predicate Device. The test results demonstrated that the Proposed Device complies with the following standards and requirements:

Biocompatibility Test
-For the components in direct contact with human body, in vitro cytotoxicity test, skin irritation test, skin sensitization test and ethylene oxide sterilization residuals test were conducted in accordance with the following standards:
● ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity
● ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
● ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation

-Shelf-life Testing
The shelf life of the Proposed Device is determined based on a stability study including accelerated aging test, which is conducted in accordance with ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

-Simulated Transportation Tests
The Proposed Device has passed the transportation validation test in accordance with ASTM D4169-22 DC13 Standard Practice for Performance Testing of Shipping Containers and Systems.

-Performance Testing
Performance testing has been conducted in accordance with the AutoGel Pad Product Technology Requirements, including appearance inspection, size measurement, pH value test, acoustic performance test (sound velocity, acoustic characteristic impedance, sound attenuation), and microbial limits test. All test results meet the defined acceptance inspection criteria and applicable standard

requirements.

-Clinical Test Conclusion
No clinical study is included in this submission.

-Final Conclusion
All non-clinical test results demonstrate that the Proposed Device complies with applicable regulatory requirements and standards, with safety and effectiveness equivalent to the legally marketed Predicate Device. No new risks that would affect the safety and effectiveness of the device are introduced, and the substantial equivalence between the Proposed Device and the Predicate Device is fully verified.