July 11, 2024

WickiMed (Huizhou) Medical Equipment Manufacturing Co.,Ltd
Haobin Li
General Manager
TangJiao XingWang Street, LiLin Town, ZhongKai Hi-Tech Zone
HuiZhou, GuangDong 516003
China

Re: K241022
Trade/Device Name: Sterile single use tip cleaner (WK800-S10 , WK800-S20)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 20, 2024
Received: May 20, 2024

Dear Haobin Li:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.07.11 15:06:45 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*

K241022

Device Name

Sterile single use tip cleaner (WK800-S10 , WK800-S20)

Indications for Use *(Describe)*

The sterile single use tip cleaner is a single use sterile device intended to be used as an electrosurgical accessory to remove eschar buildup from the tips of electrosurgical cauterization blades during surgical procedures.

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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WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.

510(K) SUMMARY

This summary of 510(K) is being submitted in accordance with the requirements of 21 CFR §807.92.

Type of submission :Traditional The assigned 510(K) number is:K241022

The date the summary was prepared: April 15, 2024

1. Submitter information:

Manufacturer Name: WickiMed(Huizhou) Medical Equipment Manufacturing Co.,Ltd.

Address: TangJiao XingWang Street, LiLin Town, ZhongKai Hi-Tech Zone, HuiZhou,GuangDong, China.

Establishment Registration Number:3010601992

Contact person:Haobin Li

Position: General Manager

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2. Device Information:

Trade/Common Name: Sterile single use tip cleaner
Models: WK800-S10 ,WK800-S20
Regulatory Class: Class II
Regulatory Number: 21 CFR 878.4400
Review Panel: General & Plastic Surgery
Product Code: GEI (Electrosurgical, Cutting & Coagulation & Accessories)

3. Predicative Device

Manufacturer: Key Surgical Incorporated
Trade/Device Name: Key Surgical® Cautery Tip Cleaner
Product Code: GEI
510(k) Number: K151222

4. Indication for Use

The sterile single use tip cleaner is a single use sterile device intended to be used as an electrosurgical accessory to remove eschar buildup from the tips of electrosurgical

cauterization blades during surgical procedures.

5. Device Description

The product has 2 sizes: 50mm(L)×50mm(W)×5mm(T) and 50mm(L)×25mm(W)× 5mm(T). The product is composed by a small foam pad with an abrasive surface, and adhesive back layer, which are used to aid in the removal of eschar on electrosurgical blades during surgical procedures. The abrasive surface is made from aluminum oxide 'gravel' with a polyurethane foam base and pressure sensitive adhesive layer containing a barium monofilament for x-ray detection. The adhesive back allows for universal placement and keeps the device in place while the tip of the electrosurgical cauterization device is scratched on the abrasive surface to remove eschar buildup. The product does not come in contact with the patient, is provided sterile and is single-use.

6. Comparison of Intended Use and Technological Characteristics

The Sterile single use tip cleaner predicate device is the Key Surgical, Inc., K151222, cleared on May 22, 2015. The following illustrates the similarities in the product design.

Table 1 : Comparison to Predicate device

Characteristics	**Predicate Device** **Key Surgical® Cautery Tip Cleaner** **K151222**	**Proposed Device** **Sterile single use tip cleaner**
Indications for Use	The disposable cautery tip cleaner is a single use sterile device intended to be used as an electrosurgical accessory to remove eschar buildup from the tips of electrosurgical cauterization blades during surgical procedures.	The sterile single use tip cleaner is a single use sterile device intended to be used as an electrosurgical accessory to remove eschar buildup from the tips of electrosurgical cauterization blades during surgical procedures.
Conditions of Use	Single Use, disposable	Single Use, disposable
Materials	Aluminum oxide 'gravel', with a polyurethane foam pad and polyurethane adhesive layer containing a barium monofilament for x-ray detection.	Aluminum oxide 'gravel' with a polyurethane foam base and pressure sensitive adhesive layer containing a barium monofilament for x-ray detection.
Adhesive back	Yes, for universal placement and aid in keeping the device in place .	Yes, for universal placement and aid in keeping the device in place .
Sterility	Provided Sterile	Provided Sterile
Principle of Operation	The cautery tip cleaner is used	The cautery tip cleaner is used

	to aid in the removal of eschar on electrosurgical blades during surgical procedures.	to aid in the removal of eschar on electrosurgical blades during surgical procedures.
Interface with Electrosurgical Cauterization Blade	The Cautery Tip Cleaner does not impact the function of the electrosurgical cauterization blades. It is not required for use with the blades, but an accessory that aids in the removal of eschar buildup.	The sterile single use tip cleaner does not impact the function of the electrosurgical cauterization blades. It is not required for use with the blades, but an accessory that aids in the removal of eschar buildup.

7. Summary of Non-clinical Performance Testing

Table 2 : Non-clinical Performance Testing

Item	**Requirement**	**Result**
1. Appearance	1.1The surface of the product should be clean, free from damage, cracking, or other undesirable phenomena.	PASS
	1.2 The product sandpaper surface, sponge base layer, pressure-sensitive adhesive, X-ray ray, and release paper should be tightly bonded together, and there should be no curling or falling off.	PASS
2.Product performance	2.1 The double-sided adhesive has good adhesion, smoothness and no warping.	PASS
	2.2 There is no sand falling off on the polishing abrasive (sandpaper) surface.	PASS
	2.3 The peel strength of the double-sided adhesive should be≥2N/CM.	PASS
3. Residual Testing	3.ETO Residual ≦4mg/pcs,ECH≦9mg/pcs.	PASS

8. Conclusion

The sterile single use tip cleaner is as safe and effective as the predicate device.