September 21, 2022

Lamidey Noury Medical
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, MN 55114

Re: K222542
Trade/Device Name: MCB UNIT Model: V10GMCBUS
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: August 22, 2022
Received: August 22, 2022

Dear Prithul Bom:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Reginald K. Avery, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K222542

Device Name
MCB UNIT Model: V10GMCBUS

Indications for Use *(Describe)*
Electrosurgical unit « MCB » is intended for use for the ablation, removal, resection, and coagulation of soft tissue, and where associated hemostasis is required in endoscopic urological surgical procedures.
The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

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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510(k) SUMMARY

510(k) Owner	LAMIDEY NOURY MEDICAL SAS ZA des Godets, 3 rue des petits ruisseaux 91370 Verrières le Buisson Phone Number: +33 1 69 20 69 69 Email Address: g.noury@lamidey-noury.fr
Contact Person	Imane OUIKENE Quality & Regulatory Manager i.ouikene@lamidey-noury.fr
510(k) Summary prepared on	2022-05-27
Device Name	Trade Name: MCB Common Name: MCB Model: V10GMCBUS
Classification	876.4300: Endoscopic electrosurgical unit and accessories
Product Code	KNS: unit, electrosurgical, endoscopic (with or without accessories)
Panel	Gastroenterology/Urology
Class	2
Predicate devices	Manufacturer: GYRUS ACMI Inc. Device Name: PK SUPERPULSE SYSTEM GENERATOR MODEL 744000 Product Code: GEI/KNS 510k Number : K100816
Device description	MCB is a reusable, non-sterile electrosurgical bipolar generator with cutting and coagulation modes. The maximum output power is 500 W. The front panel GUI (graphical user interface) features soft keys and digital displays for: ● the connection status of accessories connected to the electrosurgical generator. ● the current settings of the chosen output mode (Cut/ Coag), and possibility to adjust it ● Sound Level adjustment and LEDs (Green for Sound and Yellow/Blue for output activation) ● Electrode shortcut Alarm reset At switch on, Serial Number and Software Version are displayed MCB is intended to be used with Plasma Edge System electrodes (K213135) for endoscopic urological surgical procedures.
Indications for Use Intended Use	Electrosurgical unit « MCB » is intended for use for the ablation, removal, resection, and coagulation of soft tissue, and where associated hemostasis is required in endoscopic urological surgical procedures. The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment
Summary of the technological characteristics	MCB is an electromedical equipment, driven and controlled by Software which is able to provide to electrodes: - Clinical Performance: HF electrical power in order to generate thermal energy which induces - Clinical Benefit: Cutting/Coagulation effect for ablation, removal, resection, and coagulation of soft tissue, and hemostasis.

Electrical safety and electromagnetic compatibility testing	Validation studies for this submission are based on recognized standards: - ISO 14971 for Risks management - IEC 62304 for Software development - IEC 62366-1 for Usability - IEC 60601-2-2 for Safety of Electrosurgical Generator - IEC 60601-1-2 for EMC
Software validation	Software validation for this submission are based on this guidance: - "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005). The device software is considered a "Moderate Level ofConcern".
Usability	The MCB unit usability was assessed and found to be safe and effective for its intended uses, by the intended users, in its intended use environment.
Summary of the Clinical performance data	No other Clinical data are included in this submission
Summary of the Non-Clinical performance data	Validation study for this submission are based on this guidance: - FDA Guidance Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery (March 9, 2020).in particular for Thermal Effect studies on representative tissues for urological Application
Overall Conclusions	Comparison between device described in this 510(k) and predicate device shows a substantial equivalence based on : - Same Indications for Use, - Same technological and technical characteristics (Principle of operations) - Results of non-clinical tests Slight differences do not raise any questions regarding safety and effectiveness. Therefore, it can be concluded that device described in this 510(k) is « as Safe and effective »as the predicate device.