June 9, 2026

Sejong Medical Co., Ltd.
Jinho Kim
Manager
11 Sinchon 2-ro, Paju-si
Gyeonggi-do, 10880
Republic Of Korea

Re: K253165
Trade/Device Name: LAP-iX2N
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 22, 2026
Received: April 22, 2026

Dear Jinho Kim:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.06.09 12:29:04 -04'00'

Colin Kejing Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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.	K253165

Please provide the device trade name(s).

LAP-iX2N

Please provide your Indications for Use below.

LAP-iX2N is a sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site.

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)

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510(k) Summary – Traditional 510(K)

The assigned 510(k) Number: K253165

01. Date of Submission: Sep 26 2025

02. Applicant / Submitter

SEJONG MEDICAL CO., LTD.
11, Sinchon 2-ro, Paju-si, Gyeonggi-do, Republic of Korea

03. Submission Correspondent

JINHO KIM
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04. Subject Device Identification

Trade/Device name: LAP-iX2N
Classification Name: Sterile Single-use Suction and Irrigation Electrode
Common Name: Electrosurgical Cutting and coagulation device and accessories
Device Class: Class II
Regulation Number: 21 CFR 878.4400
Product Code: GEI
Review Panel: General & Plastic Surgery

Indication for use:

LAP-iX2N is a sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site.

05. Predicate Device Identification

510(k) Number: K200639
Device Name: LAP-iX
Manufacturer: SEJONG MEDICAL Co., Ltd.

06. Device Description

The LAP-iX2N provides suction or irrigation and conducts high-frequency monopolar electrosurgical energy from compatible electrosurgical generators to a surgical site during laparoscopic and endoscopic procedures.

It delivers sterile irrigation fluids to surgical site and evacuates blood and body fluids from the surgical site to aid visualization. They are used during endoscopic, and laparoscopic surgical procedures to ablate, remove, resect, and coagulate soft tissue where associated hemostasis is required.

Depending on the shape of the handle, there are two types, PISTOL Type and TRUMPET Type. PISTOL Type has pistol grip handle design. TRUMPET Type has Trumpet grip handle design.

The electrode offers three types: L-HOOK, SPOON and J-HOOK Type. All three electrode types are compatible with the PISTOL Type and the TRUMPET Type. The L-Hook & J-Hook electrode tip has a sharp contact surface that facilitates cutting especially for thin and long tissue. The SPOON electrode tip is mainly used for large area tissue and also for hemostasis procedure as well.

The maximum peak voltage shall not exceed 1,150 Vpeak. The electrosurgical generator should be set to the lowest effective power setting and should not exceed 100W. The connector of the subject device is compatible with all suction/irrigation pumps and electrosurgical generator in the market which have the connecting tubes or connectors of Ø10mm (Suction), Ø7mm(Irrigation) and Ø4mm(Electrode). All equipment conforming to this specs can be used.

07. Summary of Technological Characteristics Comparison

The LAP-iX2N has the same intended uses, principle of operation and similar technical characteristics and functionality as predicate devices.

Product Name	Subject Device LAP-iX2N K253165	Predicate Device LAP-IX K200639	Equivalence Discussion
Manufacturer	SEJONG MEDICAL CO.,LTD.	SEJONG MEDICAL CO.,LTD.	Same
Product code / Regulation	GEI / 21 CFR 878.4400	GEI / 21 CFR 878.4400	Same
Classification	Class II	Class II	Same
Prescription or OTC	Prescription	Prescription	Same
Intended use	During laparoscopic surgery, the Lap-iX2N is intended use to cut/coagulate soft tissue, suction/irrigation functions to the surgical site	The intended use for Lap-iX is to cut/coagulate soft tissue, suction/irrigation functions to the surgical site during laparoscopic surgery.	Same
Operation Principles	This product uses the principle that when high-frequency(RF) energy from an electrosurgical device is applied to the electrode through a cable and connector, high-frequency current is applied to the human body from the electrode, heat is generated by bio resistance, and the heat generated causes cutting,	This product uses the principle that when high-frequency(RF) energy from an electrosurgical device is applied to the electrode through a cable and connector, high-frequency current is applied to the human body from the electrode, heat is generated by bio resistance, and the heat generated causes cutting, coagulation, and hemostasis of cell tissue.	Same

	coagulation, and hemostasis of cell tissue. This product is a disposable electrode that injects liquids such as saline solution or aspirates and removes substances such as blood and body fluids, and uses the electrode to cut, coagulate, and hemostasis of tissue. Depending on the shape of the handle, there are two types: PISTOL Type and TRUMPET Type, and the electrodes are L-HOOK, J-HOOK, and SPOON Type.	This product is a disposable electrode that injects liquids such as saline solution or aspirates and removes substances such as blood and body fluids, and uses the electrode to cut, coagulate, and hemostasis of tissue. Depending on the shape of the handle, there are two types: PISTOL Type and TRUMPET Type, and the electrodes are L-HOOK, J-HOOK, and SPOON Type.	
Power source	No internal power source. The device is powered by an external electrosurgical generator.	No internal power source. The device is powered by an external electrosurgical generator.	Same
Monopolar or Bipolar	Monopolar	Monopolar	Same
Electrode Type	L-HOOK, J-HOOK, and SPOON Type.	L-HOOK, J-HOOK, and SPOON Type.	Same
Max Power (w)	100w	100w	Same
Max Voltage(V)	1,150 Vpeak	175Vrsm(300Ω)	Different (Note. 1)
Physical Dimensions	1) Handle Pistol type : 119 mm Trumpet type : 160 mm 2) Suction and Irrigation Tube Pistol type : 140 mm Trumpet type : 140 mm 3) Tube and connector size Suction : Ø10mm Irrigation : Ø7mm Electrode : Ø4mm	1) Handle Pistol type : 105mm Trumpet type : 145 mm 2) Suction and Irrigation Tube Pistol type : 170 mm Trumpet type : 170 mm 3) Tube and connector size Suction : Ø10mm Irrigation : Ø7mm Electrode : Ø4mm	Different (Note. 2)
Material	Stainless Steel, polymer, ABS, Polyethylene, Silicone	Stainless Steel, polymer, ABS, Polyethylene, Silicone	Different (Note. 3)
Single Use or Reusable	Single Use	Single Use	Same
Packaging Material	PETE, Tyvek	PETE, Tyvek	Same
Single-Use/ Reuse	Single-use	Single-use	Same
Sterilization	Sterile (EO sterilization)	Sterile (EO sterilization)	Same
Shelf life	3 years	3 years	Same

The subject device described in this 510(k) has the same intended use and the same technical characteristics as the unmodified device (LAP-iX, K200639). The subject device and the predicate devices are substantially equivalent, having the same indications for use and the technological characteristics. The modifications are material change and physical dimensions. Based on the test results submitted in this 510K, we conclude that these differences do not raise a question in safety and effectiveness and the subject device is substantially equivalent to the predicate device.

Note. 1

The subject device specifies an output voltage of 1,150 Vpeak, whereas the predicate device lists 175Vrms(300Ω).
Although the numerical values differ, this is primarily due to the difference in how generator output voltage is represented, not necessarily due to an intrinsic performance discrepancy.

The predicate device adopts an RMS(Root Mean Square) voltage representation, which has historically been common in the electrosurgical device field, particularly in older U.S. market submissions.

The Vrms Valued reflects the equivalent heating effect(average power) of the waveform and is sometimes preferred for clinical interpretability, especially when generator output settings are based on average tissue effect.

However, the Vrms representation has inherent limitations.

It does not accurately capture the peak energy delivered in high-frequency, non-sinusoidal waveforms(e.g., pulsed or modulated waveforms).

It can underestimate peak voltage stress, which is critical in evaluating electrical safety parameters such as high-frequency leakage current.

In contrast, the subject device uses a Vpeak(peak voltage) representation, which is more appropriate for the following reasons:

It aligns with IEC 60601-2-2, which defines and evaluates HF leakage current using Vpeak.

It accurately reflects the maximum electrical stress applied to the patient circuit, which is important in the context of safety and insulation design.

It is the preferred unit when standardizing generator output for regulatory and test purposes.

For consistency in comparison, the 175Vrms output of the predicate device corresponds to approximately 247.5Vpeak(Vrms x $\sqrt{2}$). While the subject device's maximum output voltage is higher, both devices are within the acceptable limits of HF leakage current and meet the requirements of IEC 60601-2-2. Furthermore, their clinical effects and methods of energy delivery are comparable, supporting a conclusion of substantial equivalence despite the difference in voltage representation.

Note .2

Although there are minor differences in physical dimensions between the subject device(LAP-iX2N) and the predicate device(LAP-iX), these changes reflect ergonomic refinements based on user preferences and clinical feedback from the use of the predicate model.

Specifically, the length of the handle and suction/irrigation tubes was adjusted to improve surgeon comfort and handling during procedures. The changes were made without altering the device's functional design, energy delivery mechanism, or clinical performance.

The suction, irrigation, and electrode connector dimensions (Ø10 mm / Ø7 mm / Ø4 mm, respectively)

remain identical, ensuring full compatibility with existing accessories and surgical workflows.

Therefore, these dimensional modifications are considered non-critical design changes and do not affect the intended use, technological characteristics, or safety and effectiveness of the device compared to the predicate.

Note. 3
To support the recent material changes, biocompatibility testing was performed on the finished device, including both direct and indirect patient-contacting components. The biocompatibility evaluation was conducted in accordance with ISO 10993-1, and testing was performed and verified in accordance with ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 10993-23. The results demonstrated that the subject device is biocompatible for its intended use.

08. Non clinical Testing Data

Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified device. The device passed all of the tests based on pre-determined pass/fail criteria. We have referenced the following standards when developing and validating the subject device.

• Sterilization Validation Test in accordance with ISO11737-1
• Shelf Life Validation Test in accordance with ASTM F 1980

Cytotoxicity	ISO 10993-5
Skin Sensitization	ISO 10993-10
Intracutaneous Reactivity	ISO 10993-23
Pyrogen	USP-NF<151>
Acute systemic toxicity	ISO 10993-11
Ethylene Oxide Sterilization Residuals	ISO 10993-7

Performance Tests: Air tightness, Continuity, Dielectric Strength, HF Leakage Current, Tensile Strength, Comparative Suction and Irrigation Performance Testing

09. Clinical Testing

Clinical testing is not a requirement and has not been performed.

10. Substantial Equivalence Conclusion

Lap-iX2N and Lap-iX are substantially equivalent in all aspects, including technical characteristics, general functions, application areas and intended use. Lap-iX2N does not introduce any fundamentally new scientific technology, only slightly different in appearance, and non-clinical tests have proven that the device is substantially equivalent to the predicate device.