December 1, 2023

Surgical Principals, Inc.
Timothy Wynne
President & CEO
1625 South Tacoma Way
Tacoma, Washington 98409

Re: K230621
Trade/Device Name: LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 24, 2023
Received: October 24, 2023

Dear Timothy Wynne:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.12.01 15:03:26 -05'00'

Mark Trumbore, Ph.D.
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

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)*

Device Name
LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes

Indications for Use *(Describe)*
The LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes are intended to be used in general laparoscopic surgical procedures requiring the use of Monpolar electrosurgical cutting and/or coagulation.

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.

510(k) K230621
510(k) Summary

1. SUBMITTER'S CONTACT INFORMATION

Company: Surgical Principals, Inc.
Address: 1625 South Tacoma Way Tacoma, WA 98409
Contact Person: Timothy Wynne
Phone: 253-709-2984

2. DEVICE NAME

Trade Name – LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes
Common Name – Monopolar Laparoscopic Instruments
Regulation Number – 21 CFR 878.4400
Classification Name – Electrosurgical, Cutting & Coagulation Device and Accessories
Product Code – GEI
Device Classification – Class II
Classification Panel – General and Plastic Surgery

3. PREDICATE DEVICE

The LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes claim Substantial Equivalence to Xodus Medical, Inc. PTFE Coated Electrode Tips cleared under 510(k) K081647. Additionally, these devices claim the Unimax Medical Systems Laparoscopic Instruments cleared under 510(k) K103508 as a Secondary Predicate or Reference Device, specifically related to the Indication for Use.

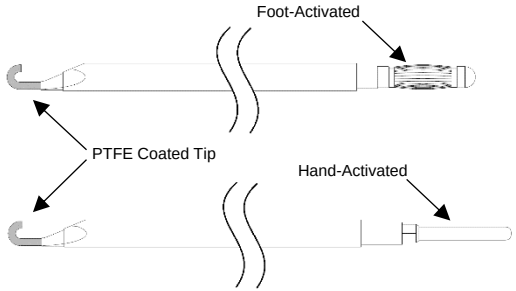
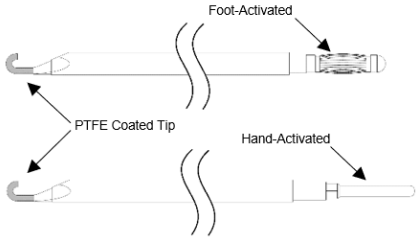
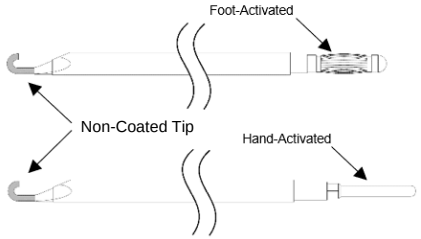
4. DEVICE DESCRIPTION

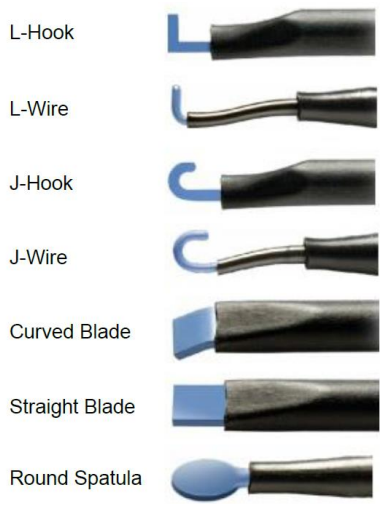
The LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes are sterile packaged single use stainless-steel electrodes coated with a non-stick material (PTFE), which is used to cut and coagulate soft tissue. The PTFE Coating reduced the buildup of eschar on the electrode during use; thus, eliminates the need to clean or "scrape" the electrode on an abrasive surface to remove the eschar buildup. These devices have a 5mm diameter with working lengths up to 44cm and includes various tip geometries (L-hook, J-Hook, Spatula, etc.). Additionally, devices are provided in either foot-activated (via a standard 4mm female monopolar connector) or hand-activated (via a standard electrosurgical pencil) versions.

5. INDICATIONS FOR USE

The LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.

6. SUBSTANTIAL EQUIVALENCE TABLE

Category	Subject Device	Primary Predicate	Secondary Predicate / Reference Device
Device	LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes (510(k) K230621)	Xodus Medical, Inc. PTFE Coated Electrode Tips (510(k) K081647)	Unimax Medical Systems, Unimax Laparoscopic Instruments (510(k) K103508)
Intended Use	The LaproGlide™ Disposable Monopolar PTFE Coated Laparoscopic Probes are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.	The intended use of this device is to conduct monopolar electrosurgical energy from an electrosurgical unit (ESU), to an electrosurgical electrode consequently to the intended tissue to be cut and/or coagulated.	The Unimax Laparoscopic Instrument is a family of instruments which includes forceps, scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.
Product Picture			
Design	These devices include a stainless-steel core with PTFE-coated tip. The device is insulated with a combination of both polyolefin and PVDF insulation and include a connector on the proximal end for either foot or hand activation.	Same	These devices include a stainless-steel core and non-coated tip. The device is insulated with polyolefin insulation and include a connector on the proximal end for either foot or hand activation.

Tip Geometries		Same	L-Hook J-Hook Round Spatula
Diameter	5 mm	Same	Same
Length	33 to 45cm	Same	26 to 45cm
Maximum Power Settings	Cutting Mode = 1600 V_p (3200 V_{p-p}) Coagulation Mode = 2900 V_p (5800 V_{p-p})	Unknown	Unknown
Biocompatibility	Conforms to ISO 10993	Same	Same
Sterilization	Sterilized using Ethylene Oxide for single patient use in accordance with ISO 11135 to an SAL of 10^-6.	Sterilized using Gamma Irradiation	Sterilized using EO Gas
Electrical Safety	IEC 60601-1 IEC 60601-2-2	Unknown	Same
Prescription Use	Yes	Yes	Yes
Intended Environment	Professional Healthcare Facility (Surgical Room or Operating theatre)	Same	Same

7. NONCLINICAL TESTS

Nonclinical testing has been conducted to verify that these devices met all design specifications and are substantially equivalent to the predicate device. Testing included the following:

- Biocompatibility Testing performed in accordance with the following:
  - ISO 10993-1: 2018 – Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (Recognition No. 2-258)
  - ISO 10993-5:2009 – Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Recognition No. 2-245)
  - ISO 10993-7:2008 – Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (Recognition No. 14-408)
  - ISO 10993-10:2021 – Biological evaluation of medical devices - Part 10: Tests for skin sensitization (Recognition No. 2-296)
  - ISO 10993-11:2017 – Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (Recognition No. 2-255)
  - ISO 10993-23:2021 – Biological evaluation of medical devices - Part 10: Tests for irritation (Recognition No. 2-291)
- Medical Electrical Equipment Safety Testing performed in accordance with the following:
  - ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) (Recognition No. 19-4)
  - IEC 60601-2-2:2017 – Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (Recognition No. 6-389)
- Aging Study
- Ethylene Oxide Sterilization Validation per ISO 11135:2014 – Sterilization of health-care products - Ethylene Oxide (Recognition No. 14-529)

In addition, these devices have been compared to the predicate device through various performance studies designed to test appearance, dimensions, corrosion resistance, operational forces, cutting efficacy and thermal effects on tissue.

Electrical performance of the device was completed following FDA guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery” issued August 15, 2016. This requires testing on three different tissue types at minimum, default, and maximum generator power in order to simulate thermal spread across different tissue types. The spread is then measured under magnification, and recorded to be compared with the predicate product. Results showed an equivalent thermal spread under the same conditions across the different tissue types and power settings. Summary results are shown below.

Table 1 – Rate of thermal damage on various tissue types

Power Level	Thermal Damage Rate on Fatty Tissues ($\bar{X} \pm \sigma^2$, mm/s)	Thermal Damage Rate on Lean Tissues ($\bar{X} \pm \sigma^2$, mm/s)	Thermal Damage Rate on Extra Lean Tissue ($\bar{X} \pm \sigma^2$, mm/s)
25W	1.21 ±0.08	1.34 ±0.14	1.65 ±0.24
50W	1.60 ±0.26	2.34 ±0.30	2.40 ±0.24
90W	3.87 ±1.65	5.15 ±4.82	5.57 ±7.59

8. CLINICAL TESTS

There were no clinical trials performed on these devices.

9. CONCLUSIONS

The subject device has equivalent indications for use as the predicate device. There are no new technologies being added to this device from the predicate, in terms of finished device functions. The device has the same intended use and application as the predicate device.