April 1, 2026

Prana Surgical
Carolyne Lu
Director of Operations
2450 Holcombe Blvd, Suite X
Houston, Texas 77021

Re: K253405
Trade/Device Name: Prana System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 25, 2026
Received: February 25, 2026

Dear Carolyne Lu:

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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.04.01 14:01:12 -04'00'

James Jang, 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.	K253405

Please provide the device trade name(s).

Prana System

Please provide your Indications for Use below.

The Prana System is intended to remove tissue and control bleeding.

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)

510(k) Summary

K253405

Date Prepared: March 27, 2026

Applicant:	Prana Surgical 2450 Holcombe Blvd, Suite X Houston, TX 77021 832-660-2827 carolyne@pranasurgical.com pranasurgical.com
Submitter:	Carolyne Lu, Director of Operations carolyne@pranasurgical.com
Alternate Contact:	Joanna Nathan, CEO joanna@pranasurgical.com

1. Device

Product code:	GEI
Regulation #	878.4400
Device Class	2
Trade Names:	Prana System
Common Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Review Panel:	OHT4A: Office of Surgical and Infection Control Devices, General & Plastic Surgery

2. Prior Submissions

There have been no prior submissions of the subject device.

3. Predicate Device

Predicate Device	510(k) Number	510(k) Holder
Bipolar Micro-Coagulation Forceps	K172368	Günter Bissinger Medizintechnik GmbH

4. Reference Device

Reference Device	510(k) Number	510(k) Holder
Resitu Slider 09 (RESL09)	K252183	Resitu Medical AB

5. Device Description

The Prana System is a bipolar electrosurgical tool intended to be used with and connected via a cable to an electrosurgical generator. The Prana System is a sterile, single-use device that allows for localization and excision of tissue using cutting and energy delivery mechanisms.

6. Indications for Use

The Prana System is intended to remove tissue and control bleeding.

7. Technological Characteristics

The technological characteristics of the Prana System are similar to the predicate, and where differences do exist, they do not raise new questions of safety and effectiveness.

	Prana System (K253405)	**Bipolar Micro-Coagulation Forceps (K172368)**	**Resitu Slider 09 (K252183)**
Regulation Number	878.4400	878.4400	876.1075
Product Code	GEI	GEI	KNW
Device Class	2	2	2
Indication for use	The Prana System is intended to remove tissue and control bleeding.	Bipolar Micro-Coagulation Forceps are intended to remove tissue and control bleeding.	Resitu Slider 09 is intended to provide breast tissue for diagnostic analysis of imaged abnormalities.
Prescription status	Prescription	Prescription	Prescription
Materials of construction	Stainless Steel and Hard Plastics	Stainless Steel and Hard Plastics	Stainless Steel and Plastics
Tip size [mm]	16	0.35 – 2.8	9
Shaft length [mm]	87.7 – 134.48	15	N/A
Electrosurgery HF-mode	Bipolar	Bipolar	Monopolar

	Prana System (K253405)	Bipolar Micro-Coagulation Forceps (K172368)	Resitu Slider 09 (K252183)
Maximum peak voltage [Vp]	90	300	N/A
Single Use	Yes	No	Yes
Sterile condition	Sterile	Unsterile	Sterile

The subject device is similar in terms of design, operating principles, and intended use and has similar technological characteristics as the predicate device. Both devices are bipolar electrosurgical devices with the same intended use. The subject and predicate devices both meet the requirements of IEC 60601-2-2.

8. Performance Data

Verification and validation results demonstrate that the subject device performs as intended and is substantially equivalent to the predicate.

8.1. Biocompatibility

The subject device has been evaluated for its biological safety according to ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process". The following endpoints have been satisfactorily completed:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity and Materials-Mediated Pyrogenicity

The evaluation confirms the biological safety of the Prana System.

8.2. Electrical Safety

The subject device has been tested according to IEC 60601-1 and IEC 60601-2-2. The device had passed all performed tests.

8.3. Mechanical Testing

The following mechanical testing was performed with the subject device:

- Compression Strength
- Tensile Strength
- Functional Testing
- Simulated Use

8.4. Sterilization and Shelf Life

The Prana System is supplied sterile and is single-use. Sterilization is by electron-beam (e-beam) utilizing a validated cycle. The Prana System has completed tests of sterility and bioburden within requirements per ISO 13004. Additionally, the Prana System has been tested for robustness in transit and found to maintain the sterile barrier integrity.

8.5. Thermal Effects on Tissue

To examine the thermal effects on tissue, the Prana System was used on cadaveric porcine tissue of three different types. The thermal damage was analyzed with histology and quantified with histomorphometry, followed by assessment to semi-quantitative (clinical impact) success criteria and found to be at or below the requirement. The results from this study, in addition to preclinical animal data, showed that in liver, kidney, lung, and muscle, there is a potential thermal spread region of up to 1.5 – 2.5 mm in the excised tissue sample and in the patient.

9. Conclusion

Based on available 510(k) information provided herein, the Prana System is considered substantially equivalent to the predicate device in terms of indications for use, material, technology, design, and performance specifications. The technological differences between the subject and the predicate device can be assured through objective testing against consensus standards and do not raise new questions of safety or effectiveness. The performance data demonstrates that the subject device is substantially equivalent to the predicate device for the requested indications for use.