January 30, 2026

Shenzhen Peninsula Medical Group
Chunyan Zhang
Director of Regulatory Affairs
101 1 F Block B, 3f Block B, 3f Block A, Bldg, F2 Changfeng
Industrial Park, Liuxian 3rd Rd., 68# Xin'An St. Bao'An Dist.
Shenzhen, 518100
China

Re: K254290
Trade/Device Name: ZenTite (Unicorn+); ZenTite (Unicorn+I); ZenTite (Unicorn+II); ZenTite (Unicorn+III)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: December 31, 2025
Received: December 31, 2025

Dear Chunyan Zhang:

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.

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: 2026.01.30 15:27:04 -05'00'

Colin K. Chen
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

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)*
K254290

Device Name
ZenTite

Indications for Use *(Describe)*
The ZenTite is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The ZenTite is used for the relief of minor muscle aches and pain, muscle spasm, and temporary improvement of local blood circulation.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

## 1. Administrative Information

**Preparation Date**

2026-01-24

**Submission Correspondent**

Name: Shenzhen Peninsula Medical Group

Address: 101 1F Block B, 3F Block B, 3F Block A, Building F2, Changfeng industrial Park, Liuxian 3rd Road, 68# Xin'an Street, Bao'an District, Shenzhen, 518100, P.R. China.

Tel: +001 949-792-8168

E-mail: zhangchunyan@peninsula-med.com

Contact: Chunyan Zhang

## 2. Device Information

**Subject Device:**

Device Name: ZenTite (Unicorn+); ZenTite (Unicorn+I); ZenTite (Unicorn+II); ZenTite (Unicorn+III)

Common Name: Electrosurgical device

Classification Name: Electrosurgical cutting and coagulation device and accessories

Regulation Medical Specialty: General & Plastic Surgery

Regulation Number: 21 CFR 878.4400

Product Code: GEI, PBX

Device Class: 2

**Predicate Device:**

| Device name | Applicant | Manufacturer and Owner of the Predicate Device | 510(k) No. |
|---|---|---|---|
| Unicorn+ RF System | Boston Aesthetics INC | Shenzhen Peninsula Medical Group | K241832 |

## 3. Indications for Use

The ZenTite is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The ZenTite is used for the relief of minor muscle aches and pain, muscle spasm, and temporary improvement of local blood circulation.

## 4. Device Description

The ZenTite system consists of a host, a footswitch, a power cord, handpieces (optional) and electrodes (optional). The treatment handle includes a handpiece, a sterilized or not sterilized electrode. There are three types of handpieces and each type is connected with one selected electrode. They are MicroRF handpiece connected with MicroRF series electrodes (MicroRF 49, MicroRF 25, MicroRF 9N, MicroRF 25N), Artist handpiece connected with Artist series electrodes (Artist D2.0, Artist D3.5, Artist D4.5, Artist D6.0) and Pure+ handpiece connected with Pure+ B1 electrode.

## 5. Comparison of Technological Characteristics with the Predicate Device

Since the previous 510(k) clearance, several modifications have been made to improve usability, workflow efficiency, and service support while maintaining the device's intended use, fundamental technology, and performance characteristics. These changes include:

(1) addition of a parameter memory function to facilitate quicker treatment setup;
(2) addition of adjustable negative-pressure levels for vacuum-assisted tips;
(3) addition of optional wireless connectivity to support remote software and firmware updates, basic device location functions, and transmission of non-sensitive operational data;
(4) update of the device trade name and corresponding user interface elements.

| Items | Subject device | Predicate device |
|---|---|---|
| Device name | ZenTite | Unicorn+ RF System |
| Principal of Operation | For MicroRF tips and Artist tips:<br>Monopolar or bipolar RF energy is delivered through micro needle electrode applying heat to target tissue to achieve coagulation and Hemostasis<br>For Pure+ tips:<br>Provide topical heating for the purpose of elevating tissue temperature for the relief of minor muscle aches and pain, muscle spasm, and temporary improvement of local blood circulation. | For MicroRF tips and Artist tips:<br>Monopolar or bipolar RF energy is delivered through micro needle electrode applying heat to target tissue to achieve coagulation and Hemostasis<br>For Pure+ tips:<br>Provide topical heating for the purpose of elevating tissue temperature for the relief of minor muscle aches and pain, muscle spasm, and temporary improvement of local blood circulation. |
| Operating Mode | Bipolar RF (Radiofrequency)<br>Monopolar RF (Radiofrequency) | Bipolar RF (Radiofrequency)<br>Monopolar RF (Radiofrequency) |
| Frequency | 1MHz | 1MHz |
| Max Output Power | 50W | 50W |
| Treatment Duration(Time) | MicroRF: 10-600 ms<br>Artist: 50-5000 ms<br>Pure+B1: 1-30 min | MicroRF: 10-600 ms<br>Artist: 50-5000 ms<br>Pure+B1: 1-30 min |
| Electrode Tips | Single electrode: Artist<br>D2.0, 2.0mm Artist<br>D3.5, 3.5mm Artist<br>D4.5, 4.5mm Artist<br>D6.0, 6.0mm Pure+B1,<br>3cm$^2$ Dual electrodes:<br>MicroRF 49, 0.5-3.5mm<br>MicroRF 25, 0.5-3.5mm MicroRF 9N,<br>0.5-3.5mm MicroRF 25N, 0.5-3.5mm | Single electrode: Artist<br>D2.0, 2.0mm Artist D3.5,<br>3.5mm Artist D4.5,<br>4.5mm Artist D6.0,<br>6.0mm Pure+B1, 3cm$^2$<br>Dual electrodes:<br>MicroRF 49, 0.5-3.5mm<br>MicroRF 25, 0.5-3.5mm MicroRF 9N, 0.5-3.5mm MicroRF 25N, 0.5-3.5mm |
| Negative-pressure level | Low: 32 kPa - 48 kPa<br>Medium: 48 kPa - 72 kPa<br>High: 56 kPa - 84 kPa | 71 kPa, ±20% |

| | | |
|---|---|---|
| Network connectivity capability | Yes | No |

# 6. Non-Clinical Performance Testing

## 6.1 Software verification and validation

Software documentation of the subject device was provided in accordance with the FDA guidance Document- "*Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff*", which was issued in 06/14/2023 to support a device's Enhanced Documentation Level.

## 6.2 Cybersecurity management activities

Cybersecurity management activities for the subject device were conducted in accordance with FDA's *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"* guidance. Activities included identification and assessment of cybersecurity risks, implementation of design controls and risk mitigations, verification of security functions, and establishment of processes for ongoing monitoring and vulnerability management. These activities support the safe and secure operation of the device without altering its intended use or performance.

## 6.3 Adjustable Negative Pressure Function Test

Bench testing was conducted to verify the effectiveness of mode selection for the adjustable negative pressure function, the adjustable pressure range (32-84 kPa), and pressure accuracy.

# 7. Conclusion

The subject device and the predicate device have the same intended use and any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness. The results of the testing described above demonstrate that the subject device is as safe and effective as the predicate device (K241832).