



4/03/2026

Newpong Co., Ltd.  
Leo W Choi  
President  
4855 Shady Pines Dr.  
Saint Cloud, Florida 34772

Re: K252495  
Trade/Device Name: LSSA (NP-200)  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction Lipoplasty System  
Regulatory Class: Class II  
Product Code: QPB  
Dated: August 8, 2025  
Received: August 8, 2025

Dear Leo W Choi:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Alicia Hemphill -S** Digitally signed by Alicia Hemphill -S  
Date: 2026.04.03 10:46:01 -05'00'

Alicia L. Hemphill (Johnson), MS  
Assistant Director  
DHT4B: Division of Plastic and  
Reconstructive 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.

K252495

?

Please provide the device trade name(s).

?

LSSA (NP-200)

Please provide your Indications for Use below.

?

LSSA is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring. LSSA is indicated for use in the following surgical specialists when the fragmentation and aspiration of adipose tissue is desired:

- Plastic and Reconstruction Surgery
- Orthopedic Surgery

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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## 510(k) Summary

1. **Date of Preparation:** March 05, 2026

2. **Applicant**

- 1) Company: NEWPONG Co., Ltd.
- 2) Address: #1212, #1216 SJ Technoville, 278, Beotkkot-ro, Geumcheon-gu, Seoul, Korea
- 3) Tel : +82-2-541-0145
- 4) Fax : +82-2-541-0147
- 5) Contact person : Leo W Choi, 786-815-9121
- 6) Contact person address : 4855 Shady Pines Dr. Saint Cloud, FL, 34772 USA
- 7) Submission date: March 05, 2026
- 8) Prior related submission : Not applicable

3. **Subject Device Information**

- 1) Trade name : LSSA (NP-200)
- 2) Common name : Suction lipoplasty system
- 3) Classification name : System, Suction, Lipoplasty For Removal
- 4) Product code : QPB
- 5) Regulation number : 878.5040
- 6) Class of device : Class II
- 7) Panel : General & Plastic Surgery

4. **Predicate Devices**

- 1) Trade name (Predicate Submission Number): LipoSaver™ (K212969)
- 2) Manufacturer: LHbiomed Co., Ltd.

5. **Device description**

LSSA (NP-200) of Newpong Co., Ltd. is an ultrasonic surgical unit designed to fragment and emulsify subcutaneous fatty tissues using ultrasound frequency vibrations. The LSSA (NP-200) generates ultrasonic vibrations through the piezoelectric effect of PZT ceramic crystals embedded in the LSSA (NP-200) handpieces. When electrical energy is supplied from the main control unit, these PZT crystals rapidly expand and contract, converting electrical signals into mechanical ultrasonic vibrations. These vibrations are transmitted to the attached probe, which delivers the mechanical action required for tissue fragmentation and emulsification.

The LSSA (NP-200) is equipped with an electronic control system that allows the operator to adjust the vibration amplitude and frequency. It offers two operating modes, Continuous Mode and Pulse Mode. And NP-200 consists of the following components: Main body (control unit) / B Handpiece / F Handpiece / Foot switch / Probes / Spanner

6. **Indications for Use:**

LSSA is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring. LSSA is indicated for use in the following surgical specialists when the fragmentation and aspiration of adipose tissue is desired:

- Plastic and Reconstruction Surgery
- Orthopedic Surgery

7. **Brief summary of Nonclinical tests and results**

- 1) Safety test

Requirement – Test		Standard	Result
Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance		IEC 60601-1	Pass
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests		IEC 60601-1-2	Pass
No.	Test item	Result	
1	IEC TS 60601-4-2:2024	Pass	
2	Ultrasound output power	Pass	

## 2) Biocompatibility

Biocompatibility of the LSSA probe was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “External communicating device – Tissue/bone/dentin” with a contact duration of “Limited (<24 hours)”.

Test item	Test method / Test criteria	Test result
Cytotoxicity test	When it was tested according to ISO 10993-5, tests for in vitro cytotoxicity-Test on extracts method, it should satisfy the requirements.	Pass
Intracutaneous reactivity test	When it was tested according to ISO 10993-23, Tests for irritation-Animal intracutaneous (intradermal) reactivity test, it should satisfy the requirements.	Pass
Skin sensitization test	When it was tested according to ISO 10993-10, Tests for skin sensitization-Guinea pig maximization test (GPMT), it should satisfy the requirements.	Pass
Acute systemic toxicity test	When it was tested according to ISO 10993-11, Tests for systemic toxicity-Acute systemic toxicity, it should satisfy the requirements.	Pass
Pyrogen Test	When it was tested according to ISO 10993-11, Tests for systemic toxicity-Information on material-mediated pyrogens, it should satisfy the requirements.	Pass

Biocompatibility of the LSSA handpiece was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “External communicating device – Tissue/bone/dentin” with a contact duration of “Limited (<24 hours)”.

Test item	Test method / Test criteria	Test result
Cytotoxicity test	When it was tested according to ISO 10993-5, tests for in vitro cytotoxicity-Test on extracts method, it should satisfy the requirements.	Pass
Intracutaneous reactivity test	When it was tested according to ISO 10993-23, Tests for irritation-Animal intracutaneous (intradermal) reactivity test, it should satisfy the requirements.	Pass
Skin sensitization test	When it was tested according to ISO 10993-10, Tests for skin sensitization-Guinea pig maximization test (GPMT), it should satisfy the requirements.	Pass
Acute systemic toxicity test	When it was tested according to ISO 10993-11, Tests for systemic toxicity-Acute systemic toxicity, it should satisfy the requirements.	Pass
Pyrogen Test	When it was tested according to ISO 10993-11, Tests for systemic toxicity-Information on material-mediated pyrogens, it should satisfy the requirements.	Pass

## 8. Substantially Equivalent (SE) Comparison

	Proposed device	Predicate device	Remark
510(k) Number	K252495	K212969	N/A
Common Name	Suction lipoplasty system	Suction lipoplasty system	Same
Trade Name	LSSA	LipoSaver™	N/A
Manufacturer	NEWPONG Co., Ltd	LHbiomed	N/A
Product Classification	ClassII	ClassII	Same
Product code	QPB	QPB	Same
Indication for use	LSSA is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring. LSSA is indicated for use in the following surgical specialists when the fragmentation and aspiration of adipose tissue is desired: - Plastic and Reconstruction Surgery - Orthopedic Surgery	LipoSaver is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring. LipoSaver is indicated for use in the following surgical specialists when the fragmentation and aspiration of soft tissue is desired: - Plastic and Reconstruction Surgery - Orthopedic Surgery	Same
Primary Function	Fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.	Fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.	Same

Operating Frequency	37.5 kHz±2%: B handpiece 31 kHz±2%: F handpiece	35kHz~40kHz	Similar(#1)
Output acoustic power	0~40W	0~40W	Same

Output mode	Continuous Mode Pulsed Mode (Duty cycle: 50%)	Continuous Mode Pulsed Mode (Duty cycle: 50%)	Same
Probe	Ø3.7, 324mm Ø2.9, 319mm Ø1.8, 121.5mm Ø1.2, 63.5mm Ø0.9, 64mm	Ø3.7, 330mm Ø2.9, 315mm Ø1.9, 121mm	Similar(#2)

**Performance Data: Safety and Performance**

	Proposed device	Predicate device	Remark
Biocompatibility	Conformed to ISO 10993-1, ISO10993-5, ISO10993-10, and ISO 10993-11	Conformed to ISO 10993-1, ISO10993-5, ISO10993-10, and ISO 10993-11	Same
Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Same
Electromagnetic Compatibility	Conformed to IEC 60601-1-2	Conformed to IEC 60601-1-2	Same

➤ **Equivalence discussion**

Similar #1 – Operating Frequency

The proposed device operates within the same ultrasonic surgical frequency band as the predicate device, as defined by IEC 61847, ensuring functional equivalence in its core technological principles. The dual-handpiece configuration of the LSSA is the result of design optimization to maintain resonant stability specifically for the five types of provided probes. Comprehensive performance testing has confirmed that stable output and operational integrity are maintained across all power settings. This configuration does not change the intended use or technological characteristics of the device and does not raise new questions of safety or effectiveness.

Similar #2 – Probe size

The proposed device offers a wider range of probe diameters (Ø0.9 mm to Ø3.7 mm) compared to the predicate device. This allows surgeons to select the most appropriate probe for various treatment areas. All probes were validated through mechanical strength testing, acoustic output measurements, and performance evaluations. These dimensional differences do not alter the intended use or technological characteristics and do not raise new concerns regarding safety or effectiveness.

## 9. Conclusion

The device was evaluated through functional and performance testing to compare its operation with that of the legally marketed predicate device.

Based on the performance data and the comparison of technological characteristics, it is concluded that LSSA of NEWPONG Co., Ltd. is substantially equivalent to the legally marketed predicate device.