February 26, 2026

ORO Co., Ltd.
James Hoon Lim
Regulatory Affairs Consultant
707, 708, 709, Geumgwang High-Tech City 789
Taejang-Ro, Gimpo-Si, Gyeonggi-Do, Republic Of Korea
Gimpo-Si, 10091
Republic Of Korea

Re: K254271
Trade/Device Name: Capri
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 30, 2025
Received: December 30, 2025

Dear James Hoon Lim:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2026.02.26 15:53:29 -05'00'

Tanisha Hithe
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.	K254271

Please provide the device trade name(s).

CAPRI

Please provide your Indications for Use below.

CAPRI is indicated for use in dermatology: incision, excision, ablation, and vaporization with hemostasis of soft tissue,
Treatment of back acne
Treatment of atrophic acne scars
Treatment of facial wrinkles
Treatment of mild to moderate acne vulgaris
Treatment of Sebaceous Hyperplasia.

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

I. SUBMITTER

ORO Co., Ltd.
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Contact Person: James Hoon Lim
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Date Prepared: Feb 08, 2026

II. DEVICE

Name of Device: CAPRI
Common Name: Powered Laser Surgical Instrument
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX

III. PREDICATE DEVICE

K041242, Candela Smoothbeam Laser System, GEX
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

CAPRI is a diode laser which delivers energy at a wavelength of 1450 nm and it is indicated for use in dermatology: incision, excision, ablation, and vaporization with hemostasis of soft tissue. Laser energy is delivered through an optical fiber that is attached to the handpiece. Laser guide tip is attached to the handpiece ensures that the spot is focused on the skin and serves as the laser beam aiming device.

CAPRI consists of the following components:

- Main Unit
- Accessories:
  - Handpiece & Laser Guide Tip
  - Foot Switch
  - Remote Interlock Connector
  - Gas Spray (HFC-134)
  - Key Switch
  - Eye Protection Goggle

V. INDICATIONS FOR USE

CAPRI is indicated for use in dermatology: incision, excision, ablation, and vaporization with hemostasis of soft tissue,
Treatment of back acne
Treatment of atrophic acne scars
Treatment of facial wrinkles
Treatment of mild to moderate acne vulgaris
Treatment of Sebaceous Hyperplasia.

Indications for Use Comparison: CAPRI and the predicate device; SMOOTHBEAM Laser System (K041242) have the same indications for use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device & Predicate Device(s):	K254271	K041242
General Device Characteristics		
Light Source	Diode Laser	Diode Laser
Wavelength	1450 nm	1450 nm
Aiming Beam	650 nm	650 nm
Spot Size	6 mm (+/- 10%)	4 mm, 6 mm (+/- 20%)
Laser Output (fluence)	4 – 12 J/cm^2	4 – 14 J/cm^2 (6 mm spot size) 8 – 25 J/cm^2 (4 mm spot size)
Pulse Duration	210 ms (52.5 ms x 4)	210 ms (52.5 ms x 4)
Repetition Rate	1 Hz	1 Hz
Cooling System	Cryogen Gas Spray	Cryogen Gas Spray
Cooling Duration	20-38 ms	20-85 ms
Activation	Footswitch and Handpiece	Footswitch

VII. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

Verification/validation activities from non-clinical testing as described below demonstrate that the differences do not raise any new issues of safety or effectiveness of the subject device compared to the predicate device.

EMC and Electrical safety of the subject device was tested in compliance with IEC 60601-1:2005/AMD1:2012/AMD2:2020 (including US National Differences) and IEC 60601-1-2:2014+A1:2020.

Device safety was tested in compliance with IEC 60601-2-22:2019 and IEC 60825-1:2014.

Laser Output Test, Wavelength Test, Pulse Width Test, Beam Profile Test, Spot Size Test and Repetition Rate Test were performed to ensure that the subject device performs as intended and meets design specifications.

Biocompatibility testing was performed in compliance with ISO 10993-1 and FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1:

Evaluation and testing within a risk management process" to demonstrate biocompatibility of the patient-contacting components of the device.

Software Verification and Validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software documentation level for the subject device is considered as 'Enhanced Documentation'.

Based on the data provided, we conclude that the subject device is as safe, as effective, and performs as well as the predicate device.

VIII. CONCLUSIONS

The CAPRI has the same indications for use and incorporates similar design and functional features as the predicate device. The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the CAPRI should perform as intended in the specified use conditions. Therefore, Capri is as safe, as effective, and performs as well as the predicate device, and no new issues of safety or effectiveness are introduced.