Review Summary

July 23, 2026
Pharmaceuticals and Medical Devices Agency

The following is the summary of the review of the following medical device submitted for marketing approval conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

Classification	:	Instrument & Apparatus 31 Medical Ablation Device
Term name	:	Diode laser
Brand name	:	Soprano Titanium
Applicant	:	Alma Lasers Japan K.K.
Date of application	:	September 30, 2025
Date of approval	:	April 28, 2026
Application classification	:	☐New medical device ☒Improved medical device (with clinical data) ☐Improved medical device (without clinical data)
New approval / partial Change		☐New Approval ☒Partial Change
Review category	:	☐Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry ☐Cardiopulmonary Circulation ☐Dentistry and Oral Medicine ☐Gastroenterology, Genitourinary, and Reproductive Medicine ☐Ophthalmology and Otorhinolaryngology ☒Orthopedic and Plastic Surgery ☐Robotics, IoT, and other devices (not classified as other categories) ☐Program D1 ☐Program D2
Items warranting special mention	:	☐Designated as medical devices with high medical need ☐Designated as specific-usage medical device ☐Application in accordance with conditional early approval system for medical devices (Type 1) ☐Application in accordance with conditional early approval system

for medical devices (Type 2: “Physical operation of items’ extrapolative and inclusive approval” (Phoenix))

☐Application in accordance with the notification on pre- and post-market rebalancing (☐1st step ☐2nd step)

☐Application in accordance with “Improvement design within approval for timely evaluation and notice” (IDATEN)

☐Designated as orphan medical device

☐Application in accordance with the 0929 notification

☐Other ( )

Expert Discussion : ☐Yes ☒No

1. Submitted data

(1) Background of the development

The purpose of this application is to unify the range of the single-wavelength (755 nm or 810 nm) irradiation handpiece, which is an existing component, with the range available globally for the skin type and compatible irradiation modes, and to add a handpiece (Trio, Trio4cm^2, TrioMAX) capable of simultaneously irradiating three wavelengths (755, 810, and 1064 nm).

(2) Non-clinical Data

The following nonclinical data were submitted (data items were based on applicant submission data).

- Electrical safety and electromagnetic compatibility: data indicating conformity with IEC 60601-1:2005 + A1:2012 + A2:2020, IEC 60601-1-2:2014+ A1（20）Ed4.1
- Electrical safety of medical laser devices: data on conformity to IEC 60601-2-22:2019
- Safety of laser products: data on conformity to IEC 60825-1:2014
- Performance evaluation: Test of laser output, cooling device, etc.
- Software Lifecycle Process: data on conformity to IEC 62304:2006 + A1:2015
- Usability engineering process: data on conformity to IEC 62366-1:2007 compliance
- Cyber security: data on conformity to JIS T 81001-5-1:2023

(3) Clinical data

The applicant submitted a clinical evaluation report that focused on the overseas literature. The outline of the clinical evaluation report is as follows (the clinical results section of the package insert is cited).

The results of the clinical evaluation of the Soprano Titanium and the previous-generation

device of Soprano ICE Platinum in combination with the three wavelengths handpiece based on the overseas clinical literature are as follows.

Number of subjects: 88 subjects

Observation period: within 6 months

Efficacy: Hair loss rates of hair density ranged from 40.3% to 78.4%. Patient satisfaction ranged from 3.25 to 4.88 on a 5-point scale.

Safety: In the AE and pain assessments, there were no episodes other than transient erythema, and the VAS pain score was minimal.

No serious or unexpected adverse events occurred, and all transient adverse events resolved.

2. Review Results

PMDA concluded that the application based on the clinical evaluation report is acceptable because the clinical efficacy caused by the intended physical effect of the product is considered to be publicly known in medical and pharmaceutical fields. As a result of the review of the submitted data, PMDA concluded that the partial change could be approved with the following approval conditions.

< Conditions for Approval>

The applicant is required to cooperate with related academic societies and take necessary actions to ensure the proper use of the product. For instance, knowledge and skills training may be provided to prescribing physicians, who must have established knowledge and experience in treating conditions relevant to long-term hair reduction, so as to enhance their prescription skills.