

K251973 Luminance Red Cold Sore Device (TN1927G)Sep 23, 2025
89 days to decisionK251973 · Product code: **OKJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251973/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Treatment For Cold Sores Herpes Simplex Virus-1 (OKJ)
Date received	Jun 26, 2025
Decision date	Sep 23, 2025
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Luminance Medical Ventures, Inc.
Location	Dallas, TX, US
Contact	Troy Stites
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Medlaunch, LLC
Contact	Nathan Glass

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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