

K260598 5 Wavelength LED Facemask (TN2508)

Jul 24, 2026
150 days to decision

K260598 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k260598/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Feb 24, 2026
Decision date	Jul 24, 2026
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	iSMART Developments, Ltd.
Location	Birmingham, GB
Contact	Susan D'Arcy
510(k) history	4 submissions · 4 cleared · 2023-2026