

K242382 décoLITE LED DeviceNov 8, 2024
88 days to decisionK242382 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Aug 12, 2024
Decision date	Nov 8, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	iSMART Developments, Ltd.
Location	Birmingham, GB
Contact	Susan D'Arcy
510(k) history	3 submissions · 3 cleared · 2023-2025

CLINICAL EVIDENCE - NCT06542341**Study to Evaluate the Efficacy of the décoLITE LED Device in Treating the Signs of Skin Aging of the décolletage Area**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	18 patients (actual)
Study sites	1 site
Condition studied	Wrinkle
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 31, 2021
Sponsor	Steven Baker (Industry)

Primary outcome

Reduction in chest lines at rest

Secondary outcome

Reduction in chest pigmentation

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06542341