

K254129 Spectrum-2

May 22, 2026
151 days to decision

K254129 · Product code: **MUD** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k254129/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Dec 22, 2025
Decision date	May 22, 2026
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neko Health AB
Location	Danderyd, SE
Contact	Per Sundström
510(k) history	2 submissions · 2 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Healthcare Innovation Catalysts, Inc.
Contact	Brittany Valdez Nava

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