FDA 510(k) Premarket Notification

K253911 Derma-2

CLEARED

May 20, 2026
163 days to decision

K253911 · Product code: **LHQ** · Radiology
Source: https://www.510kdatabase.net/k253911/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Telethermographic (adjunctive Use) (LHQ)
Date received	Dec 8, 2025
Decision date	May 20, 2026
Days to decision	163 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