FDA 510(k) Premarket Notification

K253303 Dendrite Imaging System

CLEARED

Nov 28, 2025
60 days to decision

K253303 · Product code: **QDG** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Parathyroid Autofluorescence Imaging Device (QDG)
Date received	Sep 29, 2025
Decision date	Nov 28, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dendrite Imaging, Inc.**
Location	Berkeley, CA, US
Contact	Ali Amiri
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Decus Biomedical, Inc.**
Contact	Terese Bogucki

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