

K230448 DeepX DermoSight DermatoscopeMay 17, 2023
85 days to decisionK230448 · Product code: **PSN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Imaging (PSN)
Date received	Feb 21, 2023
Decision date	May 17, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Deepx Health, LLC
Location	Washington, DC, US
Contact	Laurens Kraal
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Howard Schroyer
Contact	Howard Schroyer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230448/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026