FDA 510(k) Premarket Notification

K211617 Infrascanner

CLEARED

Feb 9, 2022
259 days to decision

K211617 · Product code: **OPT** · Neurology
Source: https://www.510kdatabase.net/k211617/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Infrared Hematoma Detector (OPT)
Date received	May 26, 2021
Decision date	Feb 9, 2022
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Infrascan, Inc.**
Location	Philadelphia, PA, US
Contact	Baruch Ben Dor
510(k) history	5 submissions · 4 cleared · 2011-2024

REGULATORY CONSULTANT

Consulting firm	**Namsa**
Contact	Angela Mallery

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