

**K211617 Infrascanner**Feb 9, 2022  
259 days to decisionK211617 · Product code: **OPT** · Neurology  
Source: <https://www.510kdatabase.net/k211617/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Namsa</b>
Contact	Angela Mallery

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211617/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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