

**K191851 VS3-IR**Nov 25, 2019  
138 days to decisionK191851 · Product code: **OWN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k191851/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Jul 10, 2019
Decision date	Nov 25, 2019
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic</b>
Location	Minneapolis, MN, US
Contact	Alex Chanin
Website	<a href="http://www.medtronic.com/us-en/index.html">http://www.medtronic.com/us-en/index.html</a>
510(k) history	33 submissions · 33 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Arazy Group Consultants, Inc.</b>
Contact	Ray Kelly

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

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