FDA 510(k) Premarket Notification

K183453 VS3-IR

CLEARED

Mar 4, 2019
81 days to decision

K183453 · Product code: **OWN** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k183453/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Dec 13, 2018
Decision date	Mar 4, 2019
Days to decision	81 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Medtronic**
Location	Minneapolis, MN, US
Contact	Alex Chanin
Website	http://www.medtronic.com/us-en/index.html
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

Consulting firm	**Arazy Group Consultants, Inc.**
Contact	Ray Kelly

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