

**K231148 ScleroSafe™ 150 mm, ScleroSafe™ 350 mm**Jun 20, 2023  
60 days to decisionK231148 · Product code: **KRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231148/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Apr 21, 2023
Decision date	Jun 20, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vvt Medical , Ltd.</b>
Location	Kfar Saba, IL
Contact	Liron Tayeb
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John J Smith

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

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