FDA 510(k) Premarket Notification

K231148 ScleroSafe™ 150 mm, ScleroSafe™ 350 mm

CLEARED

Jun 20, 2023
60 days to decision

K231148 · Product code: **KRA** · Cardiovascular
Source: https://www.510kdatabase.net/k231148/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J Smith

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