FDA 510(k) Premarket Notification

K230248 VIOLA

CLEARED

Feb 28, 2023
29 days to decision

K230248 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k230248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Clamp, Vascular (DXC)
Date received	Jan 30, 2023
Decision date	Feb 28, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vascular Graft Solutions, Ltd.**
Location	Tel Aviv, IL
Contact	Orit Yarden
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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