FDA 510(k) Premarket Notification

K241206 Quantum Perfusion Hybrid System

CLEARED

Jul 18, 2024
79 days to decision

K241206 · Product code: **DTN** · Cardiovascular
Source: https://www.510kdatabase.net/k241206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Apr 30, 2024
Decision date	Jul 18, 2024
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spectrum Medical S.R.L.**
Location	Mirandola, IT
Contact	Raffaella Tommasini
510(k) history	6 submissions · 6 cleared · 2024-2026