

K213540 Quantum SuperPAC Tubing Set, Quantum SuperPAC Cardioplegia SetMay 20, 2022
193 days to decisionK213540 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k213540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 8, 2021
Decision date	May 20, 2022
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qura S.R.L
Location	Mirandola, IT
Contact	Raffaella Tommasini
510(k) history	15 submissions · 15 cleared · 2020-2024

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