FDA 510(k) Premarket Notification

CLEARED

K203067 Quantum Perfusion Single Lumen Cannula 22F, Quantum Perfusion Dual Lumen Cannula 31F, Quantum Perfusion Dual Lumen Cannula 27F, Quantum Perfusion Dual Lumen Cannula 24F

Nov 8, 2021
395 days to decision

K203067 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k203067/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Oct 9, 2020
Decision date	Nov 8, 2021
Days to decision	395 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k203067/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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