

K201320 Quantum PureFlow Centrifugal Blood Pump CP22 with Integrated SensorNov 3, 2021
534 days to decisionK201320 · Product code: **KFM** · Cardiovascular
Source: <https://www.510kdatabase.net/k201320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	May 18, 2020
Decision date	Nov 3, 2021
Days to decision	534 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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