

**K250326 Quantum Perfusion Centrifugal Blood Pump CP22NG
with Integrated Sensors (CP22V-NG)**Jun 24, 2025
139 days to decisionK250326 · Product code: **KFM** · Cardiovascular
Source: <https://www.510kdatabase.net/k250326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Feb 5, 2025
Decision date	Jun 24, 2025
Days to decision	139 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

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