

K251783 Inspire HCR and HCR DUAL cardiotomy reservoirsDec 22, 2025
194 days to decisionK251783 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k251783/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Jun 11, 2025
Decision date	Dec 22, 2025
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sorin Group Italia S.R.L.
Location	Mirandola, IT
Contact	Martina Carlini
510(k) history	61 submissions · 61 cleared · 1995-2026

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