

K161733 INSPIRE SVR 1200, INSPIRE 6F C, INSPIRE 8F CMar 8, 2017
258 days to decisionK161733 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k161733/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Jun 23, 2016
Decision date	Mar 8, 2017
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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