

K200683 INSPIRE 7FM Hollow fiber oxygenator with integrated arterial filter, INSPIRE 7F Hollow fiber oxygenator with integrated arterial filter and hardshell reservoir, INSPIRE 7F DUAL Hollow fiber oxygenator with integrated arterial filter and hardshell reservoirJun 12, 2020
88 days to decisionK200683 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k200683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 16, 2020
Decision date	Jun 12, 2020
Days to decision	88 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	Luigi Vecchi
510(k) history	61 submissions · 61 cleared · 1995-2026

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