

K201916 Inspire 6M Hollow Fiber oxygenator, Inspire 7M Hollow Fiber oxygenator, Inspire 8M Hollow Fiber oxygenatorAug 13, 2020
34 days to decisionK201916 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k201916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 10, 2020
Decision date	Aug 13, 2020
Days to decision	34 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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