

K190690 INSPIRE 7 Hollow Fiber Oxygenator with integrated Hardshell/Venous Cardiotomy Reservoir, INSPIRE 7M Hollow Fiber Oxygenator, INSPIRE 7 Dual Hollow Fiber Oxygenator with integrated Hardshell/Venous Cardiotomy ReservoirApr 13, 2019
26 days to decisionK190690 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k190690/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 18, 2019
Decision date	Apr 13, 2019
Days to decision	26 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

REGULATORY CONSULTANT

Consulting firm	LivaNova USA, Inc.
Contact	Scott Light

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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