

K001021 LILLIPUT PHOSPHOLYPIDIC INERT SURFACE IN OXYGENATION (PH.I.S.I.O.) INFANT HOLLOW FIBRE OXYGENATOR, MODEL D902

Apr 25, 2000
26 days to decision

K001021 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k001021/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 30, 2000
Decision date	Apr 25, 2000
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dideco S.P.A.
Location	Waltham, MA, US
Contact	BARRY SALL
510(k) history	22 submissions · 22 cleared · 1997-2004

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Device record: <https://www.510kdatabase.net/k001021/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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