

**K102109 ADVANCED MEMBRANE GAS EXCHANGE (AMG),
AMG OXYGENATING MODULE, AMG VENOUS CARDIOTOMY
RESEVOIR 4500 MODEL EU5011, EU5012**Feb 15, 2011
202 days to decisionK102109 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k102109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 28, 2010
Decision date	Feb 15, 2011
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eurosets S.R.L
Location	Medolla, Modena, IT
Contact	MARIO GENMARI
510(k) history	6 submissions · 6 cleared · 2011-2025

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