

K202510 AMG PMP InfantDec 10, 2021
466 days to decisionK202510 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k202510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Aug 31, 2020
Decision date	Dec 10, 2021
Days to decision	466 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202510/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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