

K202206 AMG PMP PediatricApr 1, 2021
239 days to decisionK202206 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k202206/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received | Aug 5, 2020 |
| Decision date | Apr 1, 2021 |
| Days to decision | 239 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/k202206/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026