

**K050447 PERFORMA ADULT HOLLOW FIBER MEMBRANE OXYGENATOR**

Mar 8, 2005  
14 days to decision

K050447 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k050447/>

**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Special                                  |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received         | Feb 22, 2005                             |
| Decision date         | Mar 8, 2005                              |
| Days to decision      | 14 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Dideco S.R.L.</b>                  |
| Location       | Waltham, MA, US                       |
| Contact        | BARRY SALL                            |
| 510(k) history | 6 submissions · 6 cleared · 1996-2005 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k050447/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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