

**K133261 MEDOS HILITE 7000 & 7000 LT OXYGENATOR**Jan 9, 2014  
78 days to decisionK133261 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k133261/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Special                                  |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received         | Oct 23, 2013                             |
| Decision date         | Jan 9, 2014                              |
| Days to decision      | 78 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Medos Medizintechnik AG</b>        |
| Location       | Ann Arbor, MI, US                     |
| Contact        | Leann Christman                       |
| 510(k) history | 3 submissions · 3 cleared · 2014-2014 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133261/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 7, 2026