

**K083131 MEDOS HILITE RESERVOIR, MODEL: 4030**Jul 30, 2009  
280 days to decisionK083131 · Product code: **DTN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k083131/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Reservoir, Blood, Cardiopulmonary Bypass (DTN) |
| Date received         | Oct 23, 2008                                   |
| Decision date         | Jul 30, 2009                                   |
| Days to decision      | 280 days                                       |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Gish Biomedical, Inc.</b>            |
| Location       | Mchenry, IL, US                         |
| Contact        | JANET PEETS                             |
| 510(k) history | 75 submissions · 75 cleared · 1983-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083131/> 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 May 26, 2026