

**K090449 MEDOS HILITE INFANT OXYGENATOR, MODEL 1000,  
800 LT**Sep 18, 2009  
210 days to decisionK090449 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k090449/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 20, 2009
Decision date	Sep 18, 2009
Days to decision	210 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/k090449/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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