

**K090450 MEDOS HILITE PEDIATRIC OXYGENATOR, MODELS
2800, 2400 LT**Sep 18, 2009
210 days to decisionK090450 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k090450/>**SUBMISSION DETAILS**

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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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