

**K091062 MEDOS HILITE INFANT RESERVOIR, MODEL MVC
0730**Aug 4, 2009
112 days to decisionK091062 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k091062/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Apr 14, 2009
Decision date	Aug 4, 2009
Days to decision	112 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/k091062/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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