

K081838 GISH VISION BLOOD CARDIOPLEGIA WITH HA COATINGJan 26, 2009
210 days to decisionK081838 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k081838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Jun 30, 2008
Decision date	Jan 26, 2009
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081838/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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