

**K040355 VISION BLOOD CARDIOPLEGIA SYSTEM AND  
EXTRACORPORAL HEAT EXCHANGER WITH GBS COATING**Mar 15, 2004  
32 days to decisionK040355 · Product code: DTR · Cardiovascular  
Source: <https://www.510kdatabase.net/k040355/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Feb 12, 2004
Decision date	Mar 15, 2004
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gish Biomedical, Inc.</b>
Location	Mchenry, IL, US
Contact	J. HARVEY KNAUSS
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/k040355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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