

**K082082 GISH SVR SOFT VENOUS RESERVOIRS WITH HA COATING**Feb 4, 2009  
196 days to decisionK082082 · Product code: **DTN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k082082/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Jul 23, 2008
Decision date	Feb 4, 2009
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026