FDA 510(k) Premarket Notification

CLEARED

K964973 GISH CAP VRF45 CARDIOTOMY/VENOUS RESERVOIR

Mar 10, 1997
88 days to decision

K964973 · Product code: **DTN** · Cardiovascular
Source: https://www.510kdatabase.net/k964973/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Dec 12, 1996
Decision date	Mar 10, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k964973/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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