

K944219 SINGLE PASS BLOOD CARDIOPLEGIA SPBC SYSTEM COMPONENTSJun 30, 1995
305 days to decisionK944219 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k944219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Aug 29, 1994
Decision date	Jun 30, 1995
Days to decision	305 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944219/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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