FDA 510(k) Premarket Notification

K890504 CARDIOTOMY/AUTOTRANSFUSION/PLEURAL DRAINAGE VENOUS

CLEARED

Mar 10, 1989
37 days to decision

K890504 · Product code: **JOD** · Cardiovascular
Source: https://www.510kdatabase.net/k890504/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiotomy Suction Line, Cardiopulmonary Bypass (JOD)
Date received	Feb 1, 1989
Decision date	Mar 10, 1989
Days to decision	37 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k890504/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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