FDA 510(k) Premarket Notification

K833644 FILTER PURGE LINE EC-FPL SERIES

CLEARED

Dec 29, 1984
439 days to decision

K833644 · Product code: **DTL** · Cardiovascular
Source: https://www.510kdatabase.net/k833644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Oct 17, 1983
Decision date	Dec 29, 1984
Days to decision	439 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k833644/ 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