FDA 510(k) Premarket Notification

K870792 THORASTAT ATR-XXXX

CLEARED

Apr 28, 1987
61 days to decision

K870792 · Product code: **DTP** · Cardiovascular
Source: https://www.510kdatabase.net/k870792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Defoamer, Cardiopulmonary Bypass (DTP)
Date received	Feb 26, 1987
Decision date	Apr 28, 1987
Days to decision	61 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k870792/ 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