

**K965214 COEUR FRONT LOAD INJECTOR RETROFIT KIT
(C859-0002)**Mar 28, 1997
88 days to decisionK965214 · Product code: **DTX** · Cardiovascular
Source: <https://www.510kdatabase.net/k965214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas Control Unit, Cardiopulmonary Bypass (DTX)
Date received	Dec 30, 1996
Decision date	Mar 28, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coeur Laboratories, Inc.
Location	NC, US
Contact	James M Clinton
510(k) history	10 submissions · 10 cleared · 1983-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k965214/>; 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 June 29, 2026