

K971105 MYOTHERM (TM) XP CARDIOPLEGIA DELIVERY SYSTEMJul 11, 1997
107 days to decisionK971105 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k971105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Mar 26, 1997
Decision date	Jul 11, 1997
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Avecor Cardiovascular, Inc.
Location	Plymouth, MN, US
Contact	DENNIS E STEGER
510(k) history	9 submissions · 8 cleared · 1993-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971105/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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