

K974648 SULZER CARBOMEDICS LOW PROFILE MITRAL ROTATORAug 4, 1998
235 days to decisionK974648 · Product code: **MOP** · Cardiovascular
Source: <https://www.510kdatabase.net/k974648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rotator, Prosthetic Heart Valve (MOP)
Date received	Dec 12, 1997
Decision date	Aug 4, 1998
Days to decision	235 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sulzer Carbomedics, Inc.
Location	Austin, TX, US
Contact	EDWARD E NEWTON
510(k) history	8 submissions · 8 cleared · 1998-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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