

K980016 MILLENNIUM VALVE INTRODUCER/ROTATOR HANDLEAug 7, 1998
217 days to decisionK980016 · Product code: **MOP** · Cardiovascular
Source: <https://www.510kdatabase.net/k980016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rotator, Prosthetic Heart Valve (MOP)
Date received	Jan 2, 1998
Decision date	Aug 7, 1998
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Surgical Product (Genzyme Biosurgery)
Location	Fall River, MA, US
Contact	ROSINA ROBINSON
510(k) history	9 submissions · 8 cleared · 1998-2000

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