

K001804 NUMED Z-5 ATRIOSEPTOSTOMY CATHETERJul 12, 2000
27 days to decisionK001804 · Product code: **DXF** · CardiovascularSource: <https://www.510kdatabase.net/k001804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Septostomy (DXF)
Date received	Jun 15, 2000
Decision date	Jul 12, 2000
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	NuMED, Inc.
Location	Hopkinton, NY, US
Contact	NICHELLE LAFLESH
510(k) history	49 submissions · 47 cleared · 1985-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001804/> 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 28, 2026