

K003052 NUMED TYSHAK II AND Z-MED II PTV CATHETERSNov 1, 2000
30 days to decisionK003052 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k003052/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Oct 2, 2000
Decision date	Nov 1, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003052/> 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