

**K011557 PTA, PTV, ATRIOSEPTOSTOMY, ANGIOGRAPHIC,  
SIZING CATHETERS**Jul 12, 2001  
52 days to decisionK011557 · Product code: **DXF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k011557/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Septostomy (DXF)
Date received	May 21, 2001
Decision date	Jul 12, 2001
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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