

**K122012 Z-MED Z-MED II**Oct 4, 2012  
86 days to decisionK122012 · Product code: **OZT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k122012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Jul 10, 2012
Decision date	Oct 4, 2012
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>NuMED, Inc.</b>
Location	Hopkinton, NY, US
Contact	NICHELLE 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/k122012/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026