

**K983017 MODIFICATION TO SYSTEM 83 PLUS**Sep 22, 1998  
25 days to decisionK983017 · Product code: **NVE** · General Hospital  
Source: <https://www.510kdatabase.net/k983017/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Washer, Cleaner, Automated, Endoscope (NVE)
Date received	Aug 28, 1998
Decision date	Sep 22, 1998
Days to decision	25 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Custom Ultrasonics</b>
Location	Buckingham, PA, US
Contact	FRANK J WEBER
510(k) history	4 submissions · 4 cleared · 1984-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983017/> 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 June 9, 2026