

**K883234 TONOMITOR (TM) + SUMP**Oct 12, 1988  
72 days to decisionK883234 · Product code: **FFT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k883234/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ph, Stomach (FFT)
Date received	Aug 1, 1988
Decision date	Oct 12, 1988
Days to decision	72 days
Third-party review	No

**APPLICANT**

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Company	<b>Tonometrics, Inc.</b>
Location	Bethesda, MD, US
Contact	DONALD L MACKEEN
510(k) history	4 submissions · 4 cleared · 1988-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883234/>; 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 July 1, 2026