

K870606 TONOMITOR(TM)Apr 10, 1987
58 days to decisionK870606 · Product code: **FFT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k870606/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Ph, Stomach (FFT) |
| Date received | Feb 11, 1987 |
| Decision date | Apr 10, 1987 |
| Days to decision | 58 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|--|
| Company | Tonometrics Holdings SA C/O Mackeen Consultants |
| Location | Bethesda, MD, US |
| Contact | L MACKEEN,PHD |
| 510(k) history | 1 submissions · 1 cleared · 1987-1987 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k870606/>; 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 July 3, 2026