

K860368 URDYN 5000 (UROFLOWMETER)Apr 23, 1986
79 days to decisionK860368 · Product code: **FFO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k860368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retractor, Self-retaining (FFO)
Date received	Feb 3, 1986
Decision date	Apr 23, 1986
Days to decision	79 days
Third-party review	No

APPLICANT

Company	Dantec Electronics, Inc.
Location	Walker, MI, US
Contact	HENRIK HENRIKSEN
510(k) history	12 submissions · 12 cleared · 1985-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860368/>; 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 1, 2026