FDA 510(k) Premarket Notification

K874759 13L81 DISPOSABLE SPHINCTER ELECTRODE, 13L33 CABLE

CLEARED

Apr 14, 1988
148 days to decision

K874759 · Product code: **FAP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k874759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Nov 18, 1987
Decision date	Apr 14, 1988
Days to decision	148 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.net
Device record: https://www.510kdatabase.net/k874759/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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