FDA 510(k) Premarket Notification

K860368 URDYN 5000 (UROFLOWMETER)

CLEARED

Apr 23, 1986
79 days to decision

K860368 · Product code: **FFO** · Gastroenterology & Urology
Source: 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