FDA 510(k) Premarket Notification

K913169 DANTEC UD 5500 MK2

CLEARED

Jan 23, 1992
190 days to decision

K913169 · Product code: **FAP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k913169/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Jul 17, 1991
Decision date	Jan 23, 1992
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dantec Medical, Inc.**
Location	Mahwah, NJ, US
Contact	RICHARD D MANTHEI
510(k) history	25 submissions · 25 cleared · 1990-1996