FDA 510(k) Premarket Notification

K923117 CAVERNOSOMETRY MODULE FOR MENUET

CLEARED

Feb 22, 1993
241 days to decision

K923117 · Product code: **DXT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k923117/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jun 26, 1992
Decision date	Feb 22, 1993
Days to decision	241 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