FDA 510(k) Premarket Notification

CLEARED

K984231 ANGIOGRAPHIC CONTRAST MANAGEMENT SYSTEM, MODEL PART A AND PART B

May 31, 2000
553 days to decision

K984231 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k984231/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Nov 25, 1998
Decision date	May 31, 2000
Days to decision	553 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Invasatec**
Location	Eden Prairie, MN, US
Contact	KATE ANDERSON
510(k) history	2 submissions · 2 cleared · 1997-2000