FDA 510(k) Premarket Notification

K960430 CONTROL SYRINGE

CLEARED

Aug 6, 1996
188 days to decision

K960430 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k960430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jan 31, 1996
Decision date	Aug 6, 1996
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Scientific Device Manufacturer, LLC**
Location	San Rafael, CA, US
Contact	RICHARD C BALL
510(k) history	6 submissions · 6 cleared · 1995-1997