FDA 510(k) Premarket Notification

K991103 MODIFICATION TO ACIST CL 100H

CLEARED

May 31, 2000
426 days to decision

K991103 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k991103/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Apr 1, 1999
Decision date	May 31, 2000
Days to decision	426 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acist Medical Systems**
Location	Eden Prairie, MN, US
Contact	CARL M BEAURLINE
510(k) history	7 submissions · 7 cleared · 1999-2014