FDA 510(k) Premarket Notification

K991680 SOFTINJECT

CLEARED

Jun 3, 1999
17 days to decision

K991680 · Product code: **KZH** · General Hospital
Source: https://www.510kdatabase.net/k991680/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	May 17, 1999
Decision date	Jun 3, 1999
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Androsystems Srl**
Location	Rome, IT
Contact	ERMANNO GRECO
510(k) history	1 submissions · 1 cleared · 1999-1999