FDA 510(k) Premarket Notification

K973339 DISETRONIC PENFINE INJECTION PEN NEEDLE

CLEARED

Sep 24, 1997
19 days to decision

K973339 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k973339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 5, 1997
Decision date	Sep 24, 1997
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Disetronic Medical Systems**
Location	Minnetonka, MN, US
510(k) history	17 submissions · 13 cleared · 1991-2001