FDA 510(k) Premarket Notification

K963136 PACER MODEL 100 INFUSION CONTROLLER

CLEARED

Oct 10, 1997
423 days to decision

K963136 · Product code: **LDR** · General Hospital
Source: https://www.510kdatabase.net/k963136/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Infusion, Intravascular, Electronic (LDR)
Date received	Aug 13, 1996
Decision date	Oct 10, 1997
Days to decision	423 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Health Watch, Inc.**
Location	Broomfield, CO, US
Contact	JOHN D GREENBAUM
510(k) history	2 submissions · 2 cleared · 1992-1997