FDA 510(k) Premarket Notification

K903512 FUTURECARE CARELYNK IV SYSTEM

CLEARED

Jul 18, 1991
349 days to decision

K903512 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k903512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Aug 3, 1990
Decision date	Jul 18, 1991
Days to decision	349 days
Third-party review	No

APPLICANT

Company	**Futurecare Systems, Inc.**
Location	Findley, MN, US
510(k) history	3 submissions · 3 cleared · 1986-1991