FDA 510(k) Premarket Notification

K963375 CARDIACMONITOR

CLEARED

Feb 28, 1997
185 days to decision

K963375 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k963375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Aug 27, 1996
Decision date	Feb 28, 1997
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vision Electronics**
Location	Kirkwood, NY, US
Contact	SHAWN P WOOD
510(k) history	2 submissions · 2 cleared · 1997-1997