FDA 510(k) Premarket Notification

K904250 MODEL 4222 AMBULATORY ECG MONITOR

CLEARED

Feb 25, 1991
161 days to decision

K904250 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k904250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Sep 17, 1990
Decision date	Feb 25, 1991
Days to decision	161 days
Third-party review	No

APPLICANT

Company	**Byrncrest Global, Inc.**
Location	West Columbia, TX, US
Contact	LISA JONES
510(k) history	1 submissions · 1 cleared · 1991-1991