FDA 510(k) Premarket Notification

K823585 COMPUTER-AIDED ELECTROCARDIOGRAPH FCP-13

CLEARED

Apr 6, 1983
121 days to decision

K823585 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k823585/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Dec 6, 1982
Decision date	Apr 6, 1983
Days to decision	121 days
Third-party review	No

APPLICANT

Company	**Brentwood Instruments, Inc.**
Location	Mchenry, IL, US
510(k) history	21 submissions · 20 cleared · 1981-1990