FDA 510(k) Premarket Notification

K881488 HOLTER SCANNER

CLEARED

Sep 20, 1988
165 days to decision

K881488 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k881488/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Apr 8, 1988
Decision date	Sep 20, 1988
Days to decision	165 days
Third-party review	No

APPLICANT

Company	**Cardiodata Corp.**
Location	Northborough, MA, US
Contact	BETTY LANE
510(k) history	4 submissions · 4 cleared · 1986-1990