FDA 510(k) Premarket Notification

K841172 MONITOR ONE

CLEARED

Jul 27, 1984
130 days to decision

K841172 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k841172/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Mar 19, 1984
Decision date	Jul 27, 1984
Days to decision	130 days
Third-party review	No

APPLICANT

Company	**Qmed, Inc.**
Location	Mchenry, IL, US
Contact	RICHARD I LEVINE
510(k) history	11 submissions · 11 cleared · 1984-1998