FDA 510(k) Premarket Notification

K812131 PORTAPULSE

CLEARED

Sep 21, 1981
55 days to decision

K812131 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k812131/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jul 28, 1981
Decision date	Sep 21, 1981
Days to decision	55 days
Third-party review	No

APPLICANT

Company	**Gavon, Inc.**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1981-1981