FDA 510(k) Premarket Notification

K841363 HEART RATE/RESPIRATION SIMULATOR 8310

CLEARED

Oct 2, 1984
183 days to decision

K841363 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k841363/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Apr 2, 1984
Decision date	Oct 2, 1984
Days to decision	183 days
Third-party review	No

APPLICANT

Company	**Aequitron Medical, Inc.**
Location	Walker, MI, US
510(k) history	24 submissions · 22 cleared · 1984-1997