FDA 510(k) Premarket Notification

K832016 LME HEART-RATE MONITOR

CLEARED

Oct 26, 1983
125 days to decision

K832016 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k832016/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jun 23, 1983
Decision date	Oct 26, 1983
Days to decision	125 days
Third-party review	No

APPLICANT

Company	**Litton Medical Electronics**
Location	Walker, MI, US
510(k) history	38 submissions · 38 cleared · 1982-1985