FDA 510(k) Premarket Notification

K823904 MODEL 515 NEO-TRAK NEONATAL MONITOR

CLEARED

May 25, 1983
148 days to decision

K823904 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k823904/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Dec 28, 1982
Decision date	May 25, 1983
Days to decision	148 days
Third-party review	No

APPLICANT

Company	**Ge Medical Systems Information Technologies**
Location	Mchenry, IL, US
510(k) history	136 submissions · 132 cleared · 1978-2012