FDA 510(k) Premarket Notification

K820416 #505 PORT. VITAL FUNCTIONS NEONATAL MON

CLEARED

Mar 4, 1982
16 days to decision

K820416 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k820416/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Feb 16, 1982
Decision date	Mar 4, 1982
Days to decision	16 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