FDA 510(k) Premarket Notification

K831744 TRANSCUTANEOUS OXYGEN MONITOR OPTION

CLEARED

Jul 19, 1983
49 days to decision

K831744 · Product code: **KLK** · Anesthesiology
Source: https://www.510kdatabase.net/k831744/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	May 31, 1983
Decision date	Jul 19, 1983
Days to decision	49 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