FDA 510(k) Premarket Notification

K802046 PDS MODEL 3000 ADULT RESPIRATION MODULE

CLEARED

Sep 16, 1980
22 days to decision

K802046 · Product code: **BZQ** · Anesthesiology
Source: https://www.510kdatabase.net/k802046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Aug 25, 1980
Decision date	Sep 16, 1980
Days to decision	22 days
Third-party review	No

APPLICANT

Company	**General Electric Co.**
Location	Mchenry, IL, US
510(k) history	254 submissions · 254 cleared · 1976-2011