FDA 510(k) Premarket Notification

K800164 413A NEONATAL MONITOR

CLEARED

Apr 10, 1980
76 days to decision

K800164 · Product code: **FLS** · Anesthesiology
Source: https://www.510kdatabase.net/k800164/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Apnea, Facility Use (FLS)
Date received	Jan 25, 1980
Decision date	Apr 10, 1980
Days to decision	76 days
Third-party review	No

APPLICANT

Company	**Xerox Corp.**
Location	Walker, MI, US
Website	http://www.xerox.com
510(k) history	2 submissions · 2 cleared · 1980-1983