FDA 510(k) Premarket Notification

K800631 OXYMETER

CLEARED

Apr 2, 1980
13 days to decision

K800631 · Product code: **KLK** · Anesthesiology
Source: https://www.510kdatabase.net/k800631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	Mar 20, 1980
Decision date	Apr 2, 1980
Days to decision	13 days
Third-party review	No

APPLICANT

Company	**Dragerwerk AG**
Location	Mchenry, IL, US
510(k) history	3 submissions · 3 cleared · 1980-1991