FDA 510(k) Premarket Notification

K802978 TRANSCUTANEOUS BLOOD OXYGEN MONITOR #300

CLEARED

Feb 2, 1981
73 days to decision

K802978 · Product code: **KLK** · Anesthesiology
Source: https://www.510kdatabase.net/k802978/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	Nov 21, 1980
Decision date	Feb 2, 1981
Days to decision	73 days
Third-party review	No

APPLICANT

Company	**Brattle Instrument Corp.**
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1977-1981