FDA 510(k) Premarket Notification

K852959 PO-510 TCPO2 MONITOR

CLEARED

Nov 29, 1985
140 days to decision

K852959 · Product code: **KLK** · Anesthesiology
Source: https://www.510kdatabase.net/k852959/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	Jul 12, 1985
Decision date	Nov 29, 1985
Days to decision	140 days
Third-party review	No

APPLICANT

Company	**Sumitomo Electric Industries, Inc.**
Location	Walker, MI, US
Contact	KUNIHIKO TANIGUCHI
510(k) history	2 submissions · 2 cleared · 1981-1985