FDA 510(k) Premarket Notification

K813347 CRITIKON TRANSCUTANEOUS GAS MONITORS

CLEARED

Jan 26, 1982
60 days to decision

K813347 · Product code: **KLK** · Anesthesiology
Source: https://www.510kdatabase.net/k813347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	Nov 27, 1981
Decision date	Jan 26, 1982
Days to decision	60 days
Third-party review	No

APPLICANT

Company	**Critikon Company, LLC**
Location	Mchenry, IL, US
510(k) history	51 submissions · 51 cleared · 1979-2000