FDA 510(k) Premarket Notification

K810999 CORDIS TCPO2 TRANCUTANEOUS OXYGEN PRESS

CLEARED

Jun 24, 1981
72 days to decision

K810999 · Product code: **KLK** · Anesthesiology
Source: https://www.510kdatabase.net/k810999/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	Apr 13, 1981
Decision date	Jun 24, 1981
Days to decision	72 days
Third-party review	No

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Website	https://cordis.com
510(k) history	315 submissions · 281 cleared · 1976-2014

Cordis Corp. is a medical device manufacturer based in McHenry, US. The company specializes in interventional cardiovascular and gastroenterology devices. Cordis has a substantial FDA 510(k) regulatory history spanning from 1976 to 2014. The company received FDA 510(k) clearances from total submissions. Its portfolio focuses primarily on cardiovascular devices and gastroenterology stent systems, including percutaneous transluminal angioplasty catheters, emboli capture guidewires, and self-expanding biliary stent systems. Notable cleared products include the FLEXSTENT Bili...