FDA 510(k) Premarket Notification

K051759 FLEXI-LITE, MODEL FL-V1.2

CLEARED

Nov 17, 2005
141 days to decision

K051759 · Product code: **CBF** · Anesthesiology
Source: https://www.510kdatabase.net/k051759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Hyperbaric (CBF)
Date received	Jun 29, 2005
Decision date	Nov 17, 2005
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Performance Hyperbarics**
Location	Makawao, HI, US
Contact	SPENCER FELDMAN
510(k) history	1 submissions · 1 cleared · 2005-2005