FDA 510(k) Premarket Notification

K963917 HOLDEN-WALKER HUMIDIFIER-NEBULIZER KIT

CLEARED

Feb 25, 1997
148 days to decision

K963917 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k963917/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Sep 30, 1996
Decision date	Feb 25, 1997
Days to decision	148 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Holden Walker Corp.**
Location	Naples, FL, US
Contact	DONALD L RETALLICK, III
510(k) history	1 submissions · 0 cleared · 1997-1997