FDA 510(k) Premarket Notification

K894734 RHINOTHERM ULTRA 2

CLEARED

Feb 16, 1990
207 days to decision

K894734 · Product code: **KFZ** · Anesthesiology
Source: https://www.510kdatabase.net/k894734/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Non-direct Patient Interface (home-use) (KFZ)
Date received	Jul 24, 1989
Decision date	Feb 16, 1990
Days to decision	207 days
Third-party review	No

APPLICANT

Company	**Twinmed Products, Inc.**
Location	Santa Monica, CA, US
Contact	EDWARD J FRANK
510(k) history	1 submissions · 1 cleared · 1990-1990