FDA 510(k) Premarket Notification

K972657 ULTRAMIST 2000

CLEARED

Feb 2, 1998
202 days to decision

K972657 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k972657/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jul 15, 1997
Decision date	Feb 2, 1998
Days to decision	202 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Texas Medical Industries, Inc.**
Location	Royse City, TX, US
Contact	STEVE HARLOW
510(k) history	1 submissions · 1 cleared · 1998-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k972657/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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