FDA 510(k) Premarket Notification

K974379 ULTRANEB

CLEARED

Feb 18, 1998
90 days to decision

K974379 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k974379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 20, 1997
Decision date	Feb 18, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Bremed Italia, S.R.L.**
Location	Arnold, MO, US
Contact	MARK HEBENSTREIT
510(k) history	3 submissions · 3 cleared · 1997-1998