

K972467 STERILE WATER FOR INHALATION, USPAug 28, 1997
58 days to decisionK972467 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k972467/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jul 1, 1997
Decision date	Aug 28, 1997
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Holopack International, LP
Location	Columbia, SC, US
Contact	JOHN J BARTHE
Website	http://www.ritedose.com/
510(k) history	3 submissions · 3 cleared · 1997-1998

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