FDA 510(k) Premarket Notification

K974849 X-AIR-CISER

CLEARED

Aug 6, 1998
220 days to decision

K974849 · Product code: **BYI** · Anesthesiology
Source: https://www.510kdatabase.net/k974849/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percussor, Powered-electric (BYI)
Date received	Dec 29, 1997
Decision date	Aug 6, 1998
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hougen Mfg., Inc.**
Location	Swartz Creek, MI, US
Contact	JEFFERY R MILLER
510(k) history	2 submissions · 2 cleared · 1998-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k974849/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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