

K082657 RTX RESPIRATOROct 8, 2008
26 days to decisionK082657 · Product code: **BYT** · Anesthesiology
Source: <https://www.510kdatabase.net/k082657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, External Body, Negative Pressure, Adult (cuirass) (BYT)
Date received	Sep 12, 2008
Decision date	Oct 8, 2008
Days to decision	26 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Medivent Limited
Location	London, England, GB
Contact	SHAHAR HAYEK
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082657/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026