

**K103318 UNI-VENT 731 SERIES MODEL EMV+ PORTABLE
CRITICAL CARE VENTILATOR**

Apr 7, 2011
146 days to decision

K103318 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k103318/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Nov 12, 2010
Decision date	Apr 7, 2011
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Impact Instrumentation, Inc.
Location	Mchenry, IL, US
Contact	SUSAN MCNEVIN
510(k) history	27 submissions · 27 cleared · 1981-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k103318/> 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