

**K031064 INVACARE POLARIS EX CPAP, MODEL ISP3000**Mar 12, 2004  
344 days to decisionK031064 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k031064/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Apr 3, 2003
Decision date	Mar 12, 2004
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Invacare Corp.</b>
Location	Elyria, OH, US
Contact	JANICE BROWNLEE
Website	<a href="http://www.invacare.com/">http://www.invacare.com/</a>
510(k) history	111 submissions · 110 cleared · 1980-2007

Invacare Corp. is a healthcare company headquartered in Elyria, Ohio, specializing in mobility and respiratory care solutions. The company develops healthcare and lifestyle products focused on safety, quality, and performance for users with reduced movement. Invacare has received FDA 510(k) clearances from total submissions since its first clearance in 1980. The company's cleared devices span Physical Medicine and anesthesiology categories, including power wheelchairs, mobility scooters, standing devices, and respiratory masks. The latest FDA 510(k) clearance was in 2007,...

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