

K003561 INVACARE PASSOVER HUMIDIFIER MODEL ISP9700Apr 17, 2001
148 days to decisionK003561 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k003561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Nov 20, 2000
Decision date	Apr 17, 2001
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Invacare Corp.
Location	Elyria, OH, US
Contact	RAE ANN FARROW
Website	http://www.invacare.com/
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,...
