

K022642 TWLIGHT, MODEL ISP 9600Feb 11, 2003
187 days to decisionK022642 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k022642/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Aug 8, 2002
Decision date	Feb 11, 2003
Days to decision	187 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,...
