

K851436 NEBULAIRE (IRC 1040) NEBULIZER PUMPJul 8, 1985
89 days to decisionK851436 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k851436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Apr 10, 1985
Decision date	Jul 8, 1985
Days to decision	89 days
Third-party review	No

APPLICANT

Company	Invacare Corp.
Location	Elyria, OH, US
Contact	OTMAR H SACKERLOTSK
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,...

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