

K033819 INVACARE 3G TARSYSJun 4, 2004
178 days to decisionK033819 · Product code: ITI · Physical Medicine
Source: <https://www.510kdatabase.net/k033819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Dec 9, 2003
Decision date	Jun 4, 2004
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Invacare Corp.
Location	Elyria, OH, US
Contact	CARROLL MARTIN
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,...
