FDA 510(k) Premarket Notification

K012258 COMPANION MODEL 221, 321, 421

CLEARED

Dec 3, 2001
138 days to decision

K012258 · Product code: **INI** · Physical Medicine
Source: https://www.510kdatabase.net/k012258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vehicle, Motorized 3-wheeled (INI)
Date received	Jul 18, 2001
Decision date	Dec 3, 2001
Days to decision	138 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Golden Technologies, Inc.**
Location	Wyoming, PA, US
Contact	FRED KIWAK
510(k) history	8 submissions · 8 cleared · 1988-2006