FDA 510(k) Premarket Notification

K023906 PATHWAY CTS2000 PELVIC FLOOR TRAINING SYSTEM

CLEARED

Feb 19, 2003
89 days to decision

K023906 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k023906/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Nov 22, 2002
Decision date	Feb 19, 2003
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**The Prometheus Group**
Location	Portsmouth, NH, US
Contact	HEATHER MAGOON
510(k) history	11 submissions · 11 cleared · 1991-2016