FDA 510(k) Premarket Notification

CLEARED

K993976 PATHWAY VAGINAL EMG/STIM PERINEOMETER SENSOR, PATHWAY ANAL EMG/STIM PERINEOMETER SENSOR

Feb 22, 2000
90 days to decision

K993976 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k993976/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Nov 24, 1999
Decision date	Feb 22, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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