FDA 510(k) Premarket Notification

K993721 UROSTYM BIOFEEDBACK AND STIMULATION ANAL/RECTAL PROBES

CLEARED

Nov 29, 1999
26 days to decision

K993721 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k993721/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Nov 3, 1999
Decision date	Nov 29, 1999
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Laborie Medical Tech Corp.**
Location	Mississauga, CA
Contact	DALE COLEMAN
510(k) history	5 submissions · 5 cleared · 1995-1999