FDA 510(k) Premarket Notification

K990456 ANAL 2 ELECTRODE STIMULATION/EMG PROBE - W/STOP

CLEARED

Mar 25, 1999
41 days to decision

K990456 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k990456/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Feb 12, 1999
Decision date	Mar 25, 1999
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hollister, Inc.**
Location	Mchenry, IL, US
Contact	JOSEPH S TOKARZ
510(k) history	85 submissions · 78 cleared · 1977-2013