FDA 510(k) Premarket Notification

K891773 MICROGYN II ELEC STIM DEVICE TREAT OF URIN INCONTI

CLEARED

Aug 23, 1989
152 days to decision

K891773 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k891773/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Mar 24, 1989
Decision date	Aug 23, 1989
Days to decision	152 days
Third-party review	No

APPLICANT

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