FDA 510(k) Premarket Notification

K963222 MICROGYN PLUS STIMULATION DEVICE

CLEARED

Oct 23, 1996
68 days to decision

K963222 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k963222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Aug 16, 1996
Decision date	Oct 23, 1996
Days to decision	68 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