FDA 510(k) Premarket Notification

K891007 NONIMPLANTED ELECTRICAL CONTINENCE DEVICE

CLEARED

Jun 7, 1990
465 days to decision

K891007 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k891007/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Feb 27, 1989
Decision date	Jun 7, 1990
Days to decision	465 days
Third-party review	No

APPLICANT

Company	**Tridak Division of Indicon, Inc.**
Location	Mchenry, IL, US
Contact	CLAUDE REGNIER
510(k) history	7 submissions · 7 cleared · 1984-1990