FDA 510(k) Premarket Notification

CLEARED

K093600 OMNISTIM CONTINENCE+ PELVIC FLOOR STIMULATION SYSTEM

Dec 4, 2009
14 days to decision

K093600 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k093600/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Nov 20, 2009
Decision date	Dec 4, 2009
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	**Accelerated Care Plus**
Location	Reno, NV, US
Contact	PATRICK PARKER
510(k) history	2 submissions · 2 cleared · 2009-2016