FDA 510(k) Premarket Notification

K973096 NEOTONUS MODEL 1000 MUSCLE STIMULATOR SYSTEM

CLEARED

Jun 12, 1998
297 days to decision

K973096 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k973096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Aug 19, 1997
Decision date	Jun 12, 1998
Days to decision	297 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neotonus, Inc.**
Location	North Attleboro, MA, US
Contact	SHELIA HEMEON-HEYER
510(k) history	4 submissions · 4 cleared · 1998-2001