

K973096 NEOTONUS MODEL 1000 MUSCLE STIMULATOR SYSTEMJun 12, 1998
297 days to decisionK973096 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973096/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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