

K994109 DETRUSAN 500Aug 3, 2000
241 days to decisionK994109 · Product code: **KPI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k994109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Dec 6, 1999
Decision date	Aug 3, 2000
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovamed USA, Inc.
Location	Lehigh Acres, FL, US
Contact	E.H. CZADILEK
510(k) history	1 submissions · 1 cleared · 2000-2000

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