

K964738 ELPHA 2000 CONTIAug 14, 1997
274 days to decisionK964738 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k964738/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Nov 13, 1996
Decision date	Aug 14, 1997
Days to decision	274 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Dan Med, Inc.
Location	Denver, CO, US
Contact	THOMAS SANDGAARD
510(k) history	6 submissions · 6 cleared · 1997-2002

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