

K032988 ELPHA 4 CONTIDec 3, 2003
70 days to decisionK032988 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k032988/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Sep 24, 2003
Decision date	Dec 3, 2003
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Danmeter A/S
Location	Odense C, DK
Contact	HANNE NIELSEN
510(k) history	4 submissions · 4 cleared · 2003-2005

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