FDA 510(k) Premarket Notification

K070331 UROSTYM BIOFEEDBACK AND STIMULATION DEVICE AND ACCESSORIES

CLEARED

May 4, 2007
88 days to decision

K070331 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k070331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Feb 5, 2007
Decision date	May 4, 2007
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Laborie Medical Technologies**
Location	Williston, VT, US
Contact	BARBARA MORNET
510(k) history	1 submissions · 1 cleared · 2007-2007