

**K161055 Fuji Dynamics Incontinence Stimulation Electrode,
Models Fuji – 01/ 02/ 03/ 04/ 05/ 06/ 07/ 08/ 09/ 10/ 11/ 12/ 13/ 14/
15**Jul 12, 2016
89 days to decisionK161055 · Product code: **KPI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k161055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Apr 14, 2016
Decision date	Jul 12, 2016
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fuji Dynamics , Ltd.
Location	Hong Kong, CN
Contact	Kam Tim Ng
510(k) history	5 submissions · 5 cleared · 2011-2016

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