

K213133 Keffort (MC-100, MC-100A)Apr 13, 2022
198 days to decisionK213133 · Product code: **KPI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Sep 27, 2021
Decision date	Apr 13, 2022
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Oriental Inspiration Limited
Location	Hong Kong, CN
Contact	Francis Ko
510(k) history	5 submissions · 5 cleared · 2017-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213133/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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