

K201014 MyOnyx SystemJan 13, 2021
271 days to decisionK201014 · Product code: **KPI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k201014/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Apr 17, 2020
Decision date	Jan 13, 2021
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thought Technology , Ltd.
Location	Mchenry, IL, US
Contact	Zena Butris
510(k) history	22 submissions · 22 cleared · 1981-2022

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