

**K211463 Regulora**Nov 24, 2021  
197 days to decisionK211463 · Product code: **QMY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211463/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computerized Behavioral Therapy Device For Treating Symptoms (QMY)
Date received	May 11, 2021
Decision date	Nov 24, 2021
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Metame Health, Inc.</b>
Location	Chicago, IL, US
Contact	Tim Rudolphi
510(k) history	1 submissions · 1 cleared · 2021-2021

**CLINICAL EVIDENCE - NCT04133519****Efficacy and Safety of IBS Digital Behavioral Treatment**

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Status	Completed
Enrollment	378 patients (actual)
Study sites	1 site
Condition studied	Irritable Bowel Syndrome
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Oct 26, 2021
Sponsor	metaMe Health (Industry)

**Primary outcome**

Abdominal Pain Intensity Responder

**Secondary outcome**

Abdominal Pain Intensity

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04133519](https://clinicaltrials.gov/study/NCT04133519)