FDA 510(k) Premarket Notification

K240544 Epitomee

CLEARED

Sep 13, 2024
199 days to decision

K240544 · Product code: **QFQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240544/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ingested, Transient, Space Occupying Device For Weight Management And/or Weight Loss (QFQ)
Date received	Feb 27, 2024
Decision date	Sep 13, 2024
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Epitomee Medical , Ltd.**
Location	Caesarea, IL
Contact	Ruthie Amir
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT03610958

Safety and Performance Evaluation of the Epitomee Device for Enhancing Satiety and Weight Loss.

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	78 patients (actual)
Study sites	1 site
Condition studied	Overweight; Obesity
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 4, 2018
Sponsor	Epitomee medical (Industry)

Primary outcome

Safety evaluation of the Device administration.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03610958