FDA 510(k) Premarket Notification

K230133 Plenity

CLEARED

Jan 19, 2024
367 days to decision

K230133 · Product code: **QFQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230133/

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	Jan 17, 2023
Decision date	Jan 19, 2024
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gelesis, Inc.**
Location	Boston, MA, US
Contact	Yverre Bobay
510(k) history	2 submissions · 1 cleared · 2019-2024