FDA 510(k) Premarket Notification

K233548 Uresta®

CLEARED

Apr 3, 2024
152 days to decision

K233548 · Product code: **HHW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233548/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pessary, Vaginal (HHW)
Date received	Nov 3, 2023
Decision date	Apr 3, 2024
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Resilia, Inc.**
Location	Moncton, CA
Contact	Sam Imbeault
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**QUARAS, LLC**
Contact	Roshana Ahmed

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