FDA 510(k) Premarket Notification

K240798 Cntrl+ Bladder Support Pessary

CLEARED

Dec 17, 2024
270 days to decision

K240798 · Product code: **HHW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240798/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pessary, Vaginal (HHW)
Date received	Mar 22, 2024
Decision date	Dec 17, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cntrl+, Inc.**
Location	Cornwall, CA
Contact	Karen Brunet
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Avania Cro Canada, Inc.**
Contact	Charusheila Ramkumar

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

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Device record: https://www.510kdatabase.net/k240798/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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