December 17, 2024

Cntrl+ Inc.
℅ Charusheila Ramkumar
Consultant
Avania CRO Canada Inc.
250 Carlaw Ave., Suite 108
Toronto, ON M4M3L1
CANADA

Re: K240798
Trade/Device Name: Cntrl+ Bladder Support Pessary
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: II
Product Code: HHW
Received: November 4, 2024

Dear Charusheila Ramkumar:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240798

Device Name
Cntrl+ Bladder Support Pessary

Indications for Use *(Describe)*
The Cntrl+ Bladder Support Pessary is intended for the use in adult women, over 18 years of age who experience involuntary urine loss with physical activity (stress urinary incontinence).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TRADITIONAL 510(K) SUMMARY

1. SUBMITTER INFORMATION

Applicant	Cntrl+ Inc. 501 Campbell St. Unit 3B Cornwall, ON K6H6X5, Canada
Applicant Contact	Karen Brunet, President E-mail: karen@cntrlplus.com Phone: (613) 935-5073
Official Correspondent	Dr. Charusheila Ramkumar, E-mail: charusheila.ramkumar@avaniaclinical.com Avania CRO Canada Inc. 250 Carlaw Ave. Suite 108 Toronto, ON M4M3L1, Canada Phone: (647) 773-0974
Date Prepared	December 17, 2024

2. DEVICE NAME

Trade Name of the Device	Cntrl+ Bladder Support Pessary
Classification Name:	Pessary, Vaginal
Classification Regulation:	21 CFR 884.3575
Device Class:	II
Product Code:	HHW
Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE IDENTIFICATION

Uresta™ Pessary (K081385)

Predicate device was not subjected to any design related recall.

4. DEVICE DESCRIPTION:

The subject Pessary is designed for the management of stress urinary incontinence (SUI) in women, is a device made of medical-grade Santoprene, inserted intravaginally to support the urethra. The Cntrl+ Bladder Support Pessary reduces bladder leaks in women who are suffering from SUI by preventing or reducing unwanted urinary leakage. Use of the Cntrl+ Bladder Support Pessary is applicable for women who experience leakage when laughing, coughing, exercising, sneezing, etc. The shape of the pessary is designed to fit in the vaginal tract. The device fits most users; the correct size will be determined and prescribed by the physician. The Cntrl+ Bladder Support Pessary can be

worn daily for up to 12 hours. The Cntrl+ Bladder Support Pessary can be reused (and cleaned) for 30-90 times.

5. INDICATIONS FOR USE:

The Cntrl+ Bladder Support Pessary is intended for the use in adult women, over 18 years of age who experience involuntary urine loss with physical activity (stress urinary incontinence).

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device & Predicate Device(s)	K240798 (Subject)	K081385 (Predicate)
Device Name	Cntrl+ Bladder Support Pessary	Uresta™ Pessary
Indication For use	The Cntrl+ Bladder Support Pessary is intended for the use in adult women, over 18 years of age who experience involuntary urine loss with physical activity (stress urinary incontinence).	The device is for the use in adult women, over 18 years of age who experience involuntary urine loss with physical activity (stress urinary incontinence).
Device Type	Vaginal Pessary	Vaginal Pessary
Size (diameter in inch)	1.47-1.76	1.73-4.77
Shape	Cone-shape	Bell-shaped
Duration of use	Up to 12-hours in a 24-hour period Reusable for 90 days	Up to 24 hours and can be re-inserted after cleaning. The maximum duration of use is not specified.
Material	Bladder Support – Medical Grade Santoprene	Bladder Support – Santoprene (non-latex thermoplastic rubber)
Rx or OTC	RX	RX
Reusable or Single use	Single patient reusable	Single patient reusable

As evidenced by the above table, both the subject and the predicate devices have the same intended use but differ in technological characteristics. Performance testing was conducted on the subject device, and it was established that the differences in technological characteristics do not raise different questions of safety or effectiveness.

7. SUMMARY OF NONCLINICAL TESTING:

Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Biocompatibility testing according to ISO 10993-1:2018 - *Biological evaluation of medical devices* — Part 1: Evaluation and testing within a risk management process and FDA Guidance "*Use of International Standard ISO 10993-1*" (2016).

- Toxic shock syndrome toxin-1 (TSST-1) testing to assess if subject device enhances the growth of Staphylococcus Aureus or alters the growth of normal vaginal microflora

- The following bench performance testing were conducted per internal protocols designed by the sponsor:
    - Durability Testing
    - Compression Force Testing
    - Testing to evaluate the maximum force exerted on the vaginal wall by the subject pessary

All pre-determined acceptance criteria were met.

8. SUMMARY OF CLINICAL EVIDENCE:

Contiform is a vaginal pessary that is not marketed in the US, but it is currently marketed in Australia and United Kingdom. The design, geometry, materials and features of the Contiform and the subject device are almost identical. The only difference between the subject device and Contiform's design is the subject device uses a green colorant which is absent in Contiform pessary. A comparison including non-clinical testing was provided to demonstrate equivalence between Contiform and the subject device. Based upon this comparison, the available clinical data on Contiform were leveraged to support the safety and effectiveness of the Cntrl+ device, given the differences in physical dimensions and design of the subject device compared to the predicate device.

Data from two clinical studies conducted on Contiform were leveraged to support safety and effectiveness of the Cntrl+ in the intended population. The summary of those studies are provided below:

1. Morris, AR and Moore KH: The Contiform incontinence device – efficacy and patient acceptability Int Urogynecol. J (2003) 14: 412–417, DOI 10.1007/s00192-003-1094-8

   Location:
   St George Hospital, Sydney, Australia

   Study Design, Study Population, Primary Endpoints:
   This study had a median use of the subject pessary for 21 days (maximum 35 days) and was a prospective, single arm, clinical study that enrolled 59 subjects with dominant stress urinary incontinence or stress urinary incontinence (SUI). Forty one (41) subjects with mild, moderate, and severe SUI completed the study, with age range 42 - 53. After 3 weeks of using the Contiform device, the primary endpoint, urine loss reduction, was evaluated by using a 24-hours pad weight test. Urine loss was reduced by a median of 72% from baseline.

   Adverse events related to post treatment residual urine (N=6), acute bacterial cystitis (N=2), difficulty removing the pessary (N =3) were reported during this study. No serious adverse events were reported.

2. Allen WA, Leek H, Izurieta A and Moore KH: Update: the "Contiform" intravaginal device in four sizes for the treatment of stress incontinence Int Urogynecol. J (2008) 19:757–761, DOI 10.1007/s00192-007-0519-1

   Location:
   St George Hospital, Sydney, Australia

   Study Design, Study Population, Primary Endpoints:
   This study was 4 weeks long and was a prospective, single arm clinical study that enrolled 73 subjects with dominant stress urinary incontinence or stress urinary incontinence (SUI). Thirty seven (37) subjects with mild, moderate, and severe SUI completed the study,

with age range 41-54. After 4 weeks of using the Contiform device, the primary endpoint, urine loss reduction, was evaluated by using a 24-hours pad weight test. Urine loss was reduced by a median of 67% from the baseline and 20 women (54%) were dry (<2 g) during this test.

Adverse events related to post treatment residual urine (N=17) and difficulty removing the pessary (N =7) were reported during this study. No serious adverse events were reported.

The data leveraged from the Contiform clinical studies supports that the Ctrl+ Bladder Support Pessary can treat Stress Urinary Incontinence in the intended patient population.

9. CONCLUSIONS

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate device.