April 30, 2026

CathBuddy, Inc.
% Grace Powers
Founder/ Principal Consultant
Powers Regulatory Consulting
2451 Cumberland Pkwy. SE, Suite 3740
Atlanta, Georgia 30339

Re: DEN250023
Trade/Device Name: Aurie Reusable No-Touch Intermittent Catheter System (or Aurie System)
Regulation Number: 21 CFR 876.5120
Regulation Name: Reusable intermittent urinary catheter system
Regulatory Class: II
Product Code: SHV
Dated: June 5, 2025
Received: February 13, 2026

Dear Grace Powers:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Aurie System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Aurie Reusable No-Touch Intermittent Catheter System (or Aurie System) is indicated for the drainage of urine from the bladder for adult males requiring intermittent catheterization. Prior to use, the Aurie Catheter must be cleaned, high-level disinfected, and lubricated with the Aurie Personal Washer-Disinfector. It is for single patient reuse.

The FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Aurie System, and substantially equivalent devices of this generic type, into Class II under the generic name reusable intermittent urinary catheter system.

The FDA identifies this generic type of device as:

> **Reusable intermittent urinary catheter system.** A reusable intermittent urinary catheter system consists of a reusable intermittent urinary catheter inserted through the urethra into the bladder for urine drainage and the components necessary to reprocess the intermittent catheter. The reusable intermittent urinary catheter can be reused after reprocessing (e.g., cleaning and disinfection) with the components necessary to reprocess the intermittent catheter. The system may include cleaning and microbicidal agents, lubricant and disposable components. The reusable intermittent catheter and any reusable reprocessing components are intended for single patient reuse.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 6, 2025, FDA received your De Novo requesting classification of the Aurie System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Aurie System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Aurie System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Infection due to device malfunction or use error	Non-clinical performance testing Device characteristics Human factors testing Shelf life testing Use life testing Electrical safety testing Electromagnetic compatibility testing Wireless co-existence testing Software verification, validation, and hazard analysis Labeling
Adverse tissue reaction	Non-clinical performance testing Biocompatibility evaluation Shelf life testing Use life testing Labeling
Urinary retention	Non-clinical performance testing Labeling
Pain or discomfort	Non-clinical performance testing Human factors testing Labeling

Electrical shock or interference with other electrical components or devices	Non-clinical performance testing Electrical safety testing Electromagnetic compatibility testing Wireless co-existence testing Labeling

In combination with the general controls of the FD&C Act, the reusable intermittent urinary catheter system is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be performed:

(i) Reprocessing validation of the catheter;
(ii) Validation testing of the microbicidal process;
(iii) Catheter performance testing; and
(iv) Performance testing of components necessary to reprocess the catheter.

(2) Design characteristics must include a limitation in the number of catheter uses and a mechanism for tracking and preventing catheter use beyond the indicated use life.

(3) Human factors testing must demonstrate that the intended users(s) can safely and correctly use the device based solely on the directions for use.

(4) All patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance data must demonstrate chemical and microbiological stability of the reprocessing supplies and lubricant, packaging integrity, and device functionality over the identified shelf life.

(6) Performance data must demonstrate device functionality at the end of the identified use life.

(7) Performance data must demonstrate electromagnetic compatibility, electrical safety and wireless co-existence of the device in the intended environment.

(8) Software verification, validation, and hazard analysis must be performed.

(9) Labeling must include:

(i) Information for lay users on how the device and its components operate, including all system safety features;
(ii) Validated methods and instructions for reprocessing of any reusable components;
(iii) Maintenance instructions for the system;
(iv) A use life for reusable components; and
(v) A shelf life for the single use disposable components and reusable components as applicable.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the reusable intermittent urinary catheter system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Ángel A. Soler-García at (301) 796-6535.

Sincerely,

SHARON M. ANDREWS -S

Sharon M. Andrews
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