June 14, 2018

Compactcath, Inc.
% Tehyen Chu
Regulatory Affairs Specialist
ATOM Health Corporation
12FL, No.122 Songjiang Rd.
Taipei City, 104
Taiwan

Re: K180738
Trade/Device Name: CompactCath™ Lubricated Intermittent Urinary Catheter and OneCath™ Intermittent Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD, EZC
Dated: May 18, 2018
Received: May 25, 2018

Dear Tehyen Chu:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K180738

Device Name

CompactCath™ Lubricated Intermittent Urinary Catheter and OneCath™ Intermittent Urinary Catheter

Indications for Use *(Describe)*

CompactCath™ Lubricated Intermittent Urinary Catheter and OneCath™ Intermittent Urinary Catheter are indicated for use in male, female, and pediatric patients (adolescents and transitional adolescents) with chronic urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

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.

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May 15, 2018

# 510(k) Summary

In accordance with 21CFR 807.92, the following information is provided for the CompactCath™ Lubricated Intermittent Urinary Catheter and OneCath™ Intermittent Urinary Catheter 510(k) Premarket Notification.

## Company Information


| | |
|---|---|
| Submitter | CompactCath, Inc.<br>887 Federation Way<br>Palo Alto, CA 94303<br>Tel: 408-893-9776 |
| Contact | Naama Stauber Breckler<br>CEO |


## Device Information

| | |
|---|---|
| Trade/Device Name | CompactCath™ Lubricated Intermittent Urinary Catheter and OneCath™ Intermittent Urinary Catheter |
| Common Name | Intermittent Urinary Catheter |
| Classification | Class II |
| Regulation Number | 21 CFR 876.5130 |
| Regulation Name | Urological Catheter and Accessories |
| Primary Product Code | EZD |
| Secondary Product Code | EZC |

## Predicate Devices

- K160858 CompactCath™ Intermittent Urinary Catheter
- K140945 CompactCath™ Intermittent Urinary Catheter

## Indications for Use

CompactCath™ Lubricated Intermittent Urinary Catheter and OneCath™ Intermittent Urinary Catheter are indicated for use in male, female, and pediatric patients (adolescents and transitional adolescents) with chronic urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

May 15, 2018

## Device Description

The CompactCath™ and OneCath™ Intermittent Urinary Catheter are sterile, single use urine drainage catheter for use in draining urine from the bladder in subjects with urine drainage problems.
Both catheters will be offered in multiple French sizes (8 – 18 Fr.), lengths (10" and 16"), two tip designs (straight and coudé).

## Comparison with the predicate device

The CompactCath™ and OneCath™ Intermittent Urinary Catheter have the same technological characteristics as the predicate devices. In addition, the indications for use, clinical application, user operation, method of manufacturing, materials and packaging are all substantially equivalent.

## Performance Testing

The following performance tests were completed and the result met the acceptance criteria.

- Nonclinical functional performance testing was performed in accordance with:
  1. BS EN 1616: 1997 + A1:1999 "Sterile urethral catheters for single use" ; and
  2. ASTM F623:99 "Standard Performance Specification for Foley Catheter"
- Biocompatibility testing was conducted in accordance with:
  1. ISO 10993-1:2009 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"; and
  2. FDA Guidance "Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation of Testing."
- Sterilization validation were conducted according to:
  1. ISO 11137-1:2006 Sterilization of health care products – Radiation – Part 1; and
  2. ISO 11137-2:2013 Sterilization of health care products – Radiation – Part 2.
  3. ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
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## Conclusion

Based on the testing results provided in this premarket notification, the proposed device is as safe and effective, has the same intended use, technological characteristics and principals of operation as the predicate device. The minor differences between the two devices do not raise any new questions of safety or effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.