



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 16, 2016

Adapta Medical, Inc.
% Neil Burris
Regulatory Consultant
Neil Burris & Associates
4250 Grove Street
Denver, CO 80211

Re: K161445
Trade/Device Name: PerfIC Cath
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: July 20, 2016
Received: July 21, 2016

Dear Neil Burris:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)
Not Known K161445

Device Name
PerfIC Cath

Indications for Use (Describe)

The PerfIC Cath™ is intended for use in adult male and adult female patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals who are unable to promote natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

Section 6: 510(k) Summary

The following information is provided as required by 21 CFR §807.92 for the PerfIC Cath™ Urinary Catheter System 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor:

Adapta Medical
142 Talamine Court
Colorado Springs, CO 80907

Contact:

Name: Neil Burris
Title: Regulatory Consultant – Adapta Medical
Phone: 720 323 1662
Fax: 720 746 6390
E-mail: neil@sssnpartners.com

Submission Date: May 24, 2016

Proprietary Name: PerfIC Cath™

Common Name: Urologic Catheter and Accessories

Regulation: 21 CFR §876.5130

Regulatory Class: Class II

Product Code: EZD

Predicate Device(s):

Primary - Adapta Medical: PerfIC Cath™ (K103043)

Secondary "Reference" Predicate – Hangzhou Bever Medical Device Co., Ltd.:
Bever Medical Intermittent Catheters (K111405)

Device Description:

The PerfIC Cath™ is a single-use urinary catheter for intermittent use. The catheter is made of a simple piece of polyvinylchloride (PVC) tubing approximately 450 millimeters in length, with two (2) oval eyelet holes for intra-bladder urine drainage at the proximal tip. The tip, to be inserted through the urethra, is sealed and rounded for patient comfort and safety. The product will be available in a straight and Coude tip configuration (also termed a Tiemann tip). Additionally, the PerfIC Cath™ will be offered with either aqueous gel lubricant or hydrophilic coating. The distal end of the catheter is connected to a PVC urine collection bag. The product is available in a 14French only.

Intended Use:

The PerfIC Cath™ is intended for use in adult male and adult female patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals who are unable to promote natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

Summary of the Technological Characteristics Comparison to Predicate Device:

The PerfIC Cath™ has the same intended use and fundamental scientific technology as the predicate device. They are urinary catheters for intermittent use, with flexible insertion tips and lubricated catheter tubes for patient comfort and easy insertion, and with outer sheaths over the catheter per se so that a user can more easily maintain clean technique.

The only differences between the predicate device and the proposed device are the additional offering of curved Coude tip (Tiemann tip) versions, and hydrophilically coated versions as an alternative to aqueous gel lubricant. Versions with hydrophilic coating include a sterile water sachet for activation of the lubricant coating.

Performance Data Summary:

The modified PerfIC Cath™ catheters have been tested as required for design verification and validation. Design verification and validation testing of the new versions of the intermittent catheter included the following tests.

- Mechanical Integrity
- Advancement Force
- Biocompatibility

The product performance test results support substantial equivalence between the predicate PerfIC Cath™ and the modified PerfIC Cath™.

Substantial Equivalence:

The proposed PerfIC Cath™ device line has the same indication for use and fundamental scientific technological characteristics as the predicate device. Based on this, the design and the summary of design control activities provided in this submission, the proposed device has been shown to be substantially equivalent to the PerfIC Cath™ cleared to market under 510(k) K103043. Refer to the table below for a listing of the points compared for substantial equivalence. The modified PerfIC Cath™ devices are all substantially equivalent to the predicate PerfIC Cath™, and the curved Coude tip is substantially equivalent to the Tiemann Tip of the reference predicate, the Bever Intermittent Catheter (K111405).

Continued next page

Comparison Table Showing Substantial Equivalence between PerfIC Cath™ and predicate PerfIC Cath™

Device Attribute	PerfIC Cath™ [Straight and Coude Tip Models with either Gel or Hydrophilic Coating]	PerfIC Cath™ original Kit K103043	Equivalent
Intended Use	The PerfIC Cath™ is intended for use in adult male and adult female patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals who are unable to promote natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.	The PerfIC Cath™ is intended for use in adult male and adult female patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals who are unable to promote natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.	Identical
Packaging	Pouched kit containing catheter assembly, benzalkonium disinfectant wipe, and plastic hook; thumb holes to facilitate opening by limited dexterity patients.	Pouched kit containing catheter assembly, gauze sponge, procedure gloves, and benzalkonium disinfectant wipe, and plastic hook; thumb holes to facilitate opening by limited dexterity patients.	Substantially Equivalent
Labeling	Adhesive-backed label with preprinted information applied to sterilization pouch; Instructions for Use (IFU) supplied separately.	Adhesive-backed label with preprinted information applied to sterilization pouch; Instructions for Use (IFU) supplied separately.	Identical
Protective Cap and Lubricating Tip Assembly	Protective rigid cap with thumb loop over one-piece molded silicone-like lubricant reservoir which retains catheter tip.	Protective rigid cap with thumb loop over one-piece molded silicone-like lubricant reservoir which retains catheter tip.	Identical
Catheter Body	Straight and Coude (curved tip) 14 Fr, medium soft catheter tube with rounded, sealed proximal (patient contact) tip with two (2) offset inlet holes on opposite sides of the catheter; catheter length nominally 45 cm.	Straight 14 Fr medium soft catheter tube with rounded, sealed proximal (patient contact) tip with two (2) offset inlet holes on opposite sides of the catheter; overall catheter length nominally 40 cm.	Substantially equivalent; Coude tip substantially equivalent to Bever Medical Tiemann Tip K111405.

Device Attribute	PerfIC Cath™ [Straight and Coude Tip Models with either Gel or Hydrophilic Coating]	PerfIC Cath™ original Kit K103043	Equivalent
Protective Outer Sheath	Outer sheath over sterile catheter body made of low density polyethylene; length sufficient to seal between reservoir tip and collection bag entrance port effecting retention of catheter tip at entrance to lubricate reservoir; sheath material nominally 0.002" thick.	Outer sheath over sterile catheter body made of polypropylene with 4% silicone; length sufficient to seal between reservoir tip and collection bag entrance port effecting retention of catheter tip at entrance to lubricate reservoir; sheath material nominally 0.004" thick.	Substantially Equivalent
Urine Collection Bag	Collection bag pre-attached to catheter assembly; 1000-ml volume; flat 11 cm x 43 cm.	Collection bag pre-attached to catheter assembly; 900-ml volume; flat 11 cm x 41 cm.	Substantially Equivalent
Sterility	Entire package sterilized via ebeam irradiation to Sterility Assurance Level of 10 ⁻⁶ .	Entire package sterilized via electron beam irradiation to Sterility Assurance Level of 10 ⁻⁶ .	Identical
Biocompatibility	Patient contact materials tested according to ISO 10993-1:2009, including: Cytotoxicity, Dermal Sensitization, and Irritation (vaginal).	Patient contact materials tested according to ISO 10993-1:2009, including: Cytotoxicity, Dermal Sensitization, and Irritation (vaginal).	Substantially Equivalent
Lubricant	Aqueous lubricant gel or hydrophilic coating-with-water sachet	Aqueous lubricant gel	Substantially Equivalent
Catheter Advancement Force	Force to advance catheter through lubricant reservoir ≤ 1.5 newtons (0.33 pounds).	Force to advance catheter through lubricant reservoir ≤ 1.5 newtons (0.33 pounds).	Identical
Bond Tensile Strength	Sheath to lubricant reservoir & sheath to collection bag inlet bond strength ≥ 2.2 newtons (0.5 pounds).	Sheath to lubricant reservoir & sheath to collection bag inlet bond strength ≥ 2.2 newtons (0.5 pounds).	Identical
Overall Catheter Tensile Strength	Separation/Disassembly tensile strength of flexible reservoir component ≥ 15 newtons (3.37 pounds)	Separation/Disassembly tensile strength of flexible reservoir component ≥ 15 newtons (3.37 pounds)	Identical

Conclusions:

The modified PerfIC Cath™ devices are substantially equivalent to the predicate PerfIC Cath™, and the curved Coude tip is substantially equivalent to the reference predicate, the Bever Medical Intermittent Catheter with a Tiemann Tip.