October 1, 2018

Amsino International Inc.
Zoe Wu
RA Specialist
708 Corporate Center Drive
Pomona, CA 91768

Re: K181445
Trade/Device Name: AMSure Hydrophilic Intermittent Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: August 15, 2018
Received: August 21, 2018

Dear Zoe Wu:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181445

Device Name
AMSure® Hydrophilic Intermittent Catheter

Indications for Use *(Describe)*
INTENDED USE:
The AMSure® Hydrophilic Intermittent Catheter is inserted into the patient's bladder and indicated for intermittent use for the purpose of drainage of urine from the bladder. The catheter does not contain a balloon on its tip. An optional Water sachet is included to activate the hydrophilic-coated surface prior to use. The target populations for the subject device are Adults and Pediatrics.

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.

Section 5: 510(k) Summary

1 Submitter Information

Submitter: Amsino International Inc.
708 Corporate Center Drive, Pomona CA 91768, USA

Contact Person: Zoe Wu
RA Specialist
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Date Prepared: Sep 28, 2018

2 Device Information

Trade Name: AMSure® Hydrophilic Intermittent Catheter

Device Common Name: Urological Catheter and Accessories

Regulation Name: Urological Catheter and Accessories

Regulation Number: 21 CFR §876.5130

Product Code: EZD

Device Class: Class II

Review Panel: Gastroenterology/Urology

Table 5-1

Product Code	Description
HG971610	Hydrophilic Intermittent Catheter, 10Fr
HG971612	Hydrophilic Intermittent Catheter, 12Fr
HG971614	Hydrophilic Intermittent Catheter, 14Fr
HG971616	Hydrophilic Intermittent Catheter, 16Fr
HG971610SS	Hydrophilic Intermittent Catheter with water sachet and sleeve, 10Fr
HG971612SS	Hydrophilic Intermittent Catheter with water sachet and sleeve, 12Fr
HG971614SS	Hydrophilic Intermittent Catheter with water sachet and sleeve, 14Fr
HG971616SS	Hydrophilic Intermittent Catheter with water sachet and sleeve, 16Fr

3 Predicate Device Information

- Cure Catheter ™ Hydrophilic Coated (K132500)
- AMSure® PVC Intermittent catheter (K091306)

4 Device Description:

The AMSure® Hydrophilic Intermittent Catheter is a urethral catheter intended to be passed through the urethra during urinary catheterization and into the bladder to drain urine. It is hydrophilic and lubricous coated flexible tube owns a hydrophilic polymer in the surface which makes the catheter highly lubricious and good adhesion upon contact with water, saline solution, body fluids. The catheter and gripper is manufactured with medical grade PVC, the surface is coated with a hydrophilic low-friction coating (polyvinyl pyrrolidone, or PVP), the water sachet is with USP grade sterile water. Each catheter is provided in sterile, single-use packages, intended to be used by adults and pediatrics.

5 Intended use

The AMSure® Hydrophilic Intermittent Catheter is inserted into the patient's bladder and indicated for intermittent use for the purpose of drainage of urine from the bladder. The catheter does not contain a balloon on its tip. An optional Water sachet is included to activate the hydrophilic-coated surface prior to use. The target populations for the subject device are Adults and Pediatrics.

6 Product Comparison Summary

The proposed AMSure® Hydrophilic Intermittent Catheter and the predicate devices are intended for patients who drain the urine from bladder. These products are urethral catheters that have the same technological characteristics and material for tubing and funnel, same intended use, similar indications for use, the same function, and the same general characteristics.

The design and materials of the proposed devices are identical to the predicate Cure CatheterTM Hydrophilic Coated (K132500) and AMSure® PVC Intermittent catheter (K091306).

7 Nonclinical Testing

- Biocompatibility Testing

Cytotoxicity, Sensitization and Irritation have been conducted per ISO 10993-5 and ISO 10993-10. The Biocompatibility testing demonstrated the biological safety of the proposed devices which may directly contact the patients.

- Performance Testing

Performance Testing of AMSure® Hydrophilic Intermittent Catheter was conducted as below:

Table 5-2

SN	Test items
1	Packaging inspection
2	Appearance inspection
3	Leakage
4	Kink resistance
5	Strength test
6	Connector security
7	Flow test
8	Friction value
9	Chemical performance: Reducing matter
10	Chemical performance: pH value
11	Chemical performance: Metal ions
12	Chemical performance: EO residue
13	Biological performance: Sterility
14	Physical performance: Water sachet
15	Chemical performance: sterile water
16	Aging (shelf life/stability testing)
17	Human factor testing

8 Conclusions

The information provided within this pre-market notification demonstrates that the AMSure® Hydrophilic Intermittent Catheter is substantially equivalent to the predicate devices.