May 29, 2020

Control Medical Technology
Shawn Fojtik
President
2757 South 300 West Suite F (ZIEN)
Salt Lake City, Utah 84115

Re: K200629
Trade/Device Name: Aspire Mechanical Aspirator G
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: April 30, 2020
Received: May 01, 2020

Dear Shawn Fojtik:

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/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 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 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,

For Alan Stevens
Assistant Director
THT3C1: Injection Devices
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200629

Device Name

Aspire Mechanical Aspirator G

Indications for Use *(Describe)*

The Aspire Aspirator G is a piston syringe to inject fluids into, or aspirate fluids from, the body.

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

[X] 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:

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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."

5. 510(k) Summary K200629

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

1. **Submitter**

Control Medical Technology
2757 South 300 West
Salt Lake City, Utah 84115 USA
Phone (383) 444-2666

FDA Establishment Registration Number: #3007282893

Contact

Control Medical Technology
2757 South 300 West
Salt Lake City, Utah 84115 USA
Phone (383) 444-2666

Date of Preparation: May 28, 2020

2. **Subject Device**

Trade Name:	Aspire Mechanical Aspirator G ("Aspire Aspirator G" and/or "Subject Device")
Common Name:	Syringe and Aspirator
Classification Name:	Syringe, Piston
Product Code:	FMF
Regulation:	Class II, 21 CFR 880.5860

3. **Predicate Device**

Trade Names:	Aspire Mechanical Aspirator K072299 ("Aspire Aspirator" and/or "Predicate")
Common Name:	Syringe and Aspirator
Classification Name:	Syringe, Piston
Product Code:	FMF
Regulation:	Class II, 21 CFR 880.5860

PREDICATE DEVICE

Aspire Aspirator
K072299. Also K113757 and K131998

SUBJECT DEVICE

Aspire Aspirator G

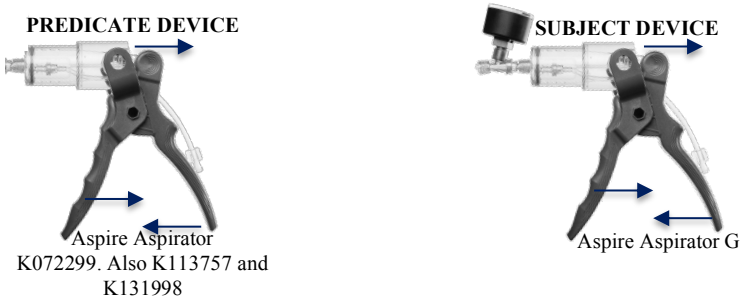
4. Reference Device

Trade Name:	PowrSyringe K072345
Common Name:	Syringe and Aspirator
Classification Name:	Syringe, Piston
Product Code:	FMF
Regulation:	Class II, 21 CFR 880.5860

Reference device utilized in submission because the pressure gauge is the same material, assembly, and processes as Subject Device.

5. Device Description

The Subject Device is a single-use, hand-held, and general-purpose aspirator configured with a barrel, plunger, and handles. The front handle is pivotally connected the back handle and distally connected to the barrel. The back handle is pivotally connected to the front handle and distally connected to the plunger. Squeezing the handles creates a mechanical advantage to move the plunger inside the barrel. The handle design also prevents the plunger from being pulled completely out of the barrel during use.



Aspire Aspirator K072299. Also K113757 and K131998

Aspire Aspirator G

The Subject Device's design, intended use, fundamental scientific principle, operation, technology, actuation, use, barrel, plunger, front handle, back handle, button, dimensions, luers, connectors, polymers, molding, assembly, packaging, and sterilization is the same as the Predicate. Users may connect pressure gauges to Predicate during use. The main difference between the Subject Device and the Predicate is the addition of a basic off-the-shelf pressure gauge and change from a one-piece to two-piece button between the handles.

6. Indications for Use

The Subject Device is the same Indication as the Predicate: The Subject Device is a piston syringe to inject fluids into, or aspirate fluids from, the body.

7. Comparison to Predicate Devices

The Subject Device is substantially equivalent to the Predicate based on equivalence in:

Same Science
Same Fundamental Scientific Principle

Same Device Construction

Design	Mechanism of Action
Mechanical Function	Manufacturing
Valves	Dimensions
Barrels	Plungers
Handles	

Same Labeling

Same Indication for Use	Instructions for Use
Warnings	

Same Manufacturing

Molding	Assembly
Packaging	Sterilization

	Predicate Control Medical Technology Aspire Aspirator K072299	**Subject Device Control Medical Technology Aspire Aspirator G**	**Comments**
Common Name	Syringe and Aspirator	Syringe and Aspirator	Same as Predicate.
Classification Name	Syringe, Piston	Syringe, Piston	Same as Predicate.
Committee	General Hospital	General Hospital	Same as Predicate.
FDA Product Code	FMF	FMF	Same as Predicate.
Regulation	Class II, 21 CFR 880.5860	Class II, 21 CFR 880.5860	Same as Predicate.
Intended Use	The Aspire Aspirator is a piston syringe to inject fluids into, or aspirate fluids from, the body.	The Aspire Aspirator G is a piston syringe to inject fluids into, or aspirate fluids from, the body.	Same as Predicate.
Fundamental Scientific Principle	The front handle is pivotally connected to the back handle and distally connected to the barrel. The back handle is pivotally connected to the front handle and distally connected to the plunger. Squeezing the handles creates a mechanical advantage to move the plunger inside the barrel. The handle design also prevents the plunger from being pulled completely out of the barrel during use.	The front handle is pivotally connected to the back handle and distally connected to the barrel. The back handle is pivotally connected to the front handle and distally connected to the plunger. Squeezing the handles creates a mechanical advantage to move the plunger inside the barrel. The handle design also prevents the plunger from being pulled completely out of the barrel during use.	Same as Predicate.
Mechanism	Handle design creates mechanical advantage to move the plunger into and out of the barrel.	Handle design creates mechanical advantage to move the plunger into and out of the barrel.	Same as Predicate.
User Control	Manual	Manual	Same as Predicate.

Barrels	Polycarbonate	Polycarbonate	Same as Predicate.
Barrel Volume	30ml	30ml	Same as Predicate.
Barrel Length	9.5cm	9.5cm	Same as Predicate.
Barrel Outer Diameter	3.5cm	3.5cm	Same as Predicate.
Barrel Tip	ISO Luer lock	ISO Luer lock	Same as Predicate.
Plunger	Polycarbonate	Polycarbonate	Same as Predicate.
Plunger Length	12cm	12cm	Same as Predicate.
O-ring	Yes	Yes	Same as Predicate.
O-ring & Barrel Lubricant	Med 400	Med 400	Same as Predicate.
Plunger Retention?	Yes, Handle design prevents plunger from being pulled out of barrel when handles are fully squeezed.	Yes, Handle design prevents plunger from being pulled out of barrel when handles are fully squeezed.	Same as Predicate.
Front Handle	Two-piece polycarbonate	Two-piece polycarbonate	Same as Predicate.
Front Handle Length	16.75cm	16.75cm	Same as Predicate.
Front Handle Width	1.75cm	1.75cm	Same as Predicate.
Back Handle	Two-piece snap together polycarbonate	Two-piece snap together polycarbonate	Same as Predicate.
Back Handle Length	16.50cm	16.50cm	Same as Predicate.
Back Handle Width	1.75cm	1.75cm	Same as Predicate.
Spring	Torsion springe	Torsion spring	Same as Predicate.
Pressure Gauge	Users may connect a separate pressure gauge to the Predicate.	Subject Device includes a pressure gauge.	Users may connect a separate pressure gauge to the Predicate. Same gauge as Reference Device.
Drain Bag and connecting tubing?	Yes $\geq$250ml	Yes $\geq$250ml	Same as Predicate.
Valve at tip?	Yes	Yes	Same as Predicate.
Valve at plunger?	Yes	Yes	Same as Predicate.
Packaging	Tray, Tyvek Lid, and Box	Tray, Tyvek Lid, and Box	Same Tray, Tyvek lid, and Box as Predicate.
Sterilization	ETO	ETO	Same sterilization as Predicate.

Same Instruction for Use?	Yes	Yes	Same IFU for Predicate and Subject Device.
Single Use Device?	Yes, Single Use	Yes, Single Use	Same as Predicate.
Bio-compatibility?	Yes. ISO 10993 compliant	Yes. ISO 10993 compliant	Same as Predicate. No new materials. Barrels, plungers, and tubing are the exact same as Predicate.

8. **Non-clinical Tests.**
   Bench testing confirms the Subject Device performs same as the Predicate including:
   - Operational & Actuation Tests
   - Vacuum Integrity Tests
   - ISO 7886-1:2017 Annex B Barrel Leakage Tests
   - ISO 7886-1:2017 Annex B Plunger Leakage Tests
   - ISO 7886-1:2017 Annex B Luer Leakage Tests
   - ISO 80369-20:2015 Annex D Fluid Seal Integrity Tests
   - MIL-STD-1472F Button Force Tests
   - ISO 10993-1 Biocompatibility
   - ISO 11135-1:2014 Sterilization to achieve SAL 10^6 and EO/ECH limits below ISO 10993-7 standards
   - ISO 1167-1:2006 Packaging Integrity Tests
   - ASTM F1608 Package Integrity Tests
   - ASTM D4169 Shipping Integrity Tests

9. **Clinical Tests.** No clinical study is required or included.

10. **Conclusion.** The Subject Device is substantially equivalent to the Predicate based on comparison of the device classification, product code, basic operating principle, fundamental scientific technology, indication for use, technical characteristics, packaging, and sterilization methods. Testing confirms the suitability of Subject Device for its intended use.

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