November 3, 2023

Guangzhou Easycess Medical Co., Ltd
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K233428
Trade/Device Name: Easycess Aspiration Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: October 11, 2023
Received: October 11, 2023

Dear Prithul Bom:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.11.03 11:40:25 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical

and Infection Control 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: 06/30/2023
See PRA Statement below.

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

Device Name
Easycess Aspiration Pump

Indications for Use *(Describe)*
The Easycess Aspiration Pump is intended for general suction use in hospitals or clinics.

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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510(k) Summary

I. SUBMITTER

Guangzhou Easycess Medical Co., Ltd
Room 701, Building B4, 11 Kaiyuan Avenue, Huangpu District, Guangzhou, China, 510530
Phone: +86 020-31603990
Fax: +86 020-31603675
Contact Person: Xingcheng Liu
Date Prepared: September 26, 2023

II. DEVICE

Name of Device: Easycess Aspiration Pump
Common or Usual Name: Aspiration Pump
Classification Name: Powered suction pump (21 CFR 878.4780)
Regulatory Class: II
Product Code: JCX
Review Panel: General & Plastic Surgery
Regulation number: 21 CFR 878.4780

III. PREDICATE DEVICE

Predicate Device: Penumbra Pump MAX (K122756)

IV. DEVICE DESCRIPTION

The Easycess Aspiration Pump is mainly composed of negative pressure suction pump host and Easycess Canister(Model：DC1000).

The Easycess Aspiration Pump is designed to provide general suction for use in hospitals or clinics. The Aspiration Pump operates using AC power and is designed to be portable if needed. The Aspiration Pump provides vacuum of up to 29 inHg. The pump is available in 110V and 220Vac versions. The pump is used with the available 1000ml canister / tubing set.

The Easycess Aspiration Pump is provided in non-sterile; it is reusable and should be managed as a prescription device. The Easycess Canister is for single use only.

V. INTENDED USE/INDICATIONS FOR USE

The Easycess Aspiration Pump is intended for general suction use in hospitals or clinics.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technological Comparison:

Item		Penumbra Pump MAX (Predicate device)		Easycess Aspiration Pump (Subject device)		Comments
Classification Name		Apparatus, Suction, Ward Use, Portable, AC-Powered		Apparatus, Suction, Ward Use, Portable, AC-Powered		Same
Class		II		II		Same
Product Code		JCX		JCX		Same
Intended Use		The Penumbra Pump MAX™ is intended for general suction use in hospitals or clinics.		The Easycess Aspiration Pump is intended for general suction use in hospitals or clinics.		Same
Pump Type/Vacuum Source		Oil-less, piston, integrated vacuum pump		Oil-less, piston, integrated vacuum pump		Similar, no substantial difference
Electrical requirement	Voltage	100-115V ac	230V ac	110V ac	220 V ac	Similar, different description
	Frequency	50Hz;60Hz	50Hz	60Hz	50Hz	Similar, different description
Vacuum Range		0-29 inHg (0-98.2 kPa)		0-29 inHg (0-98.2 kPa)		Same
Maximum vacuum pressure		29 inHg (98.2 kPa)		29 inHg (98.2 kPa)		Same
Vacuum Regulator		Stepless, mechanical		Stepless, mechanical		Same
Vacuum feedback lamp		/		Yes		Different, indicator to show the pump is ready for aspiration
Flow Rate		0-0.8 SCFM(0-23 LPM)		0-0.8 SCFM(0-23 LPM)		Same
Maximum flow rate		0.8 SCFM(23 LPM)		0.8 SCFM(23 LPM)		Same
Noise		<60 dBa		≤70 dBa		Similar
Dimensions		15.5 in×11.2 in×13.2 in (39.37 cm×28.45 cm×33.53 cm)		7.9 in×16.5 in×11.8 in (20 cm×42 cm×30cm)		Similar, both are portable
Weight		22.3 lb (10.1kg)		10.5 kg		Similar, both are portable
Canister Filter		Yes		Yes		Similar, air filter
Pump filter		None		Yes		Different, additional protection
Accessories		One set of disposable canister and connection tubing		One set of disposable canister and connection tubing		Same
Fluid Collection Disposal		Disposable collection canister		Disposable collection canister		Same
Disposable Canister Volume		1L		1L		Same
Overflow protection		Yes		Yes		Similar, both could fulfill the overflow protection
Aspiration Mode		Continuous		Continuous		Same
Single Patient Use		Single use cannister and aspiration tubing.		Single use cannister and aspiration tubing.		Same

Item	Penumbra Pump MAX (Predicate device)	Easycess Aspiration Pump (Subject device)	Comments
	Reusable pump.	Reusable pump.	
OTC or Prescription	Prescription	Prescription	Same
Duty Cycle	Non-continuous duty [45 min (97.8%) ON / 1 min(2.2%) OFF]	Non-continuous duty [45 min (97.8%) ON / 1 min(2.2%) OFF]	Same
Service Life	500 Hours	500 Hours	Same
IEC60601-1 Compliance	Yes	Yes	Same
IEC60601-1-2 Compliance	Yes	Yes	Same
Operating environment	Temp: 65°F~75°F (18°C~ 24°C) Humidity: <75% RH	Temp: 65°F~75°F (18°C~ 24°C) Humidity: <75% RH	Same
Operating atmospheric pressure	Sea Level – 6000 ft (1829m)	Sea Level – 6000 ft (1829m)	Same
Storage environment	Temp: -20°F~120°F (-29°C~ 49°C) Humidity: <95% RH	Temp: -20°F~120°F (-29°C~ 49°C) Humidity: <95% RH	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

- **Bench testing**

The bench testing covered physical and mechanical performance of the Easycess Aspiration Pump and was conducted according to the FDA special control guidance document: Guidance Document for Powered Suction Pump 510(k)s, and the ISO 10079-1:2022 Medical suction equipment - Part 1: Electrically powered suction equipment. These tests verified the performance characterization of the Easycess Aspiration Pump. All the test results from the performance testing passed the acceptance criteria set forth by the design specifications. The results of bench test are listed in table below:

Test	Specification	Conclusion
Appearance	The surface of the product is clear, the shell component has no burr sharp edge, the assembly splicing fixed firmly, no obvious gap, loose.	The appearance is suitable for intended clinical use. The subject device is equivalent to the predicate device.
Vacuum levels	10s vacuum levels ≥60.0Kpa(18 inHg)	The vacuum level is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Free air flows	Free air flows ≥20L/min	The free air flow is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to

Test	Specification	Conclusion
		the predicate device.
Final vacuum	-98.2Kpa±7 Kpa(-29 inHg±2inHg)	The final vacuum is suitable for intended clinical use . The subject device is equivalent to the predicate device.
Vacuum adjustment range	-98.2Kpa(-29 inHg)	The vacuum adjustment range is suitable for intended clinical use . The subject device is equivalent to the predicate device.
Liquid level	Clearly show the level of contents.	The liquid level is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Volume	Volume ≥1L	The volume is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Strength	Collection containers shall not implode, crack or permanently deform after 5 minutes of continuous pumping at atmospheric pressure of -95 Kpa.	The strength is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Vacuum level indicators	The full scale of analogue vacuum level indicators shall be≤ 60 inHg. Analog displays shall have graduations≥ 2mm apart with each with each graduation representing≤ 5% of the full-scale value.	The vacuum level indicators is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Vacuum level indicators accuracy	Digital displays shall indicate the vacuum level at intervals≤ 5% of the full-scale value.	The vacuum level indicators accuracy is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Operating position	When placed at any position on an incline at an Angle of (10±1) °with the horizontal plane, the equipment meets the requirements for use.	The operating position is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Overfill protection devices	Overfill protection devices shall not activate until at least 90% of the indicated maximum capacity of the collection container has been reached. When an overfill protection devices is activated, suction shall cease and prevent＞ 5ml of fluid from passing downstream of the overfill protection device within 2min.	The overfill protection devices is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Noise	The maximum A-weighted sound pressure level (steady or peak value) ≤70 dB(A).	The noise is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to

Test	Specification	Conclusion
		the predicate device.
Pharyngeal suction equipment	Suction equipment intended for pharyngeal suction shall evacuate ≥200ml of simulated vomitus in not more than 10s.	The pharyngeal suction equipment is suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Negative pressure values and flow performance requirements - Power interruption	The interruption and restoration of the power supply of the suction device should not cause any danger, and the change of the negative pressure value and flow rate should not exceed ±10% of the set value. The same performance requirement applies if the original power supply is replaced by another power supply.	The negative pressure values and flow performance requirements - Power interruption is suitable for intended clinical use and met requirements of ISO 10079-1. The subject device is equivalent to the predicate device.
Simulated use	The pump could provide stable vacuum in accompany with compatible devices.	Device performs as intended under simulated use conditions. The subject device is equivalent to the predicate device.
Connections	With the company's production of disposable suction pipe, and suitable for the vast majority of the market suction extension tube.	The connections are suitable for intended clinical use and met requirements of ISO 10079-1 and 10079-4. The subject device is equivalent to the predicate device.
Work cycle	Non-continuous duty [45min(97.8%) ON/ 1 min (2.2%) OFF]	The work cycle is suitable for intended clinical use . The subject device is equivalent to the predicate device.
Vacuum feedback lamp	When the device runs to vacuum less than -85 Kpa, the vacuum feedback light will turn on.	The negative pressure feedback lamp is suitable for intended clinical use .

- **Electromagnetic Compatibility and Electrical Safety**

The Electromagnetic Compatibility and Electrical Safety testing for the Easycess Aspiration Pump was conducted in accordance with IEC 60601-1: 2020 and IEC 60601-1-2, the results of testing are listed in the table below:

Test	Conclusion
Safety Test (IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1 General requirements for basic safety and essential performance)	Comply with IEC 60601-1.
EMC Test (IEC60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests)	Comply with IEC60601-1-2.

- **Performance Testing –Clinical**

Clinical study was not needed to demonstrate substantial equivalence.

VIII. CONCLUSIONS

The data presented in this submission demonstrates the technological similarity and equivalency of the Easycess Aspiration Pump when compared with the predicate device Penumbra Pump MAX (K122756).

The devices,

- have the same indications,
- use the same operating principle,
- incorporate the same basic design,
- are packaged using similar material and sterilized with same processes.

In summary, the Easycess Aspiration Pump described in this submission is substantially equivalent to the predicate device and should perform comparably to the predicate device marketed for the same intended use.