February 22, 2024

Anoxia Medical Inc.
% Bosmat Friedman-Cox
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K232831
Trade/Device Name: Quiver Aspiration Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA, JCX
Dated: September 13, 2023
Received: September 13, 2023

Dear Bosmat Friedman-Cox:

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; 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: 2024.02.22 08:17:47 -05'00'

Mark Trumbore, Ph.D., GWCPM
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team

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.

Submission Number *(if known)*

K232831

Device Name

Quiver Aspiration Pump

Indications for Use *(Describe)*

The Quiver 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.

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
PRAStaff@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."

510(k) Summary [Traditional 510(k)]
Quiver Aspiration Pump
510(k) Number K_____

1. SUBMITTER

Applicant's Name:
Anoxia Medical, Inc.
3475 Investment Blvd, #9
Hayward, CA 94545
Primary Contact:
Bosmat Friedman
Regulatory Affairs Consultant
3521 Hatwynn Rd.
Charlotte, NC 28269
Phone: 980-308-1636
bosmat.f@promedoss.com

Date Prepared: September 5, 2023

2. DEVICE

Trade Name:
Quiver Aspiration Pump

Classification Code:
Device: Pump, Portable, Aspiration (Manual Or Powered)
Product Code: BTA
Regulation No: 878.4780
Class: 2
Review Panel: General & Plastic Surgery

3. PREDICATE DEVICE

Penumbra Pump MAX, by Penumbra Inc., Product code JCX, cleared Under: K122756.

4. DEVICE DESCRIPTION

The Quiver Aspiration Pump is designed to provide general suction for use in hospitals or clinics. The Quiver Aspiration Pump provides battery powered suction for the removal or aspiration of fluids and debris. The Pump is a portable, single-use, non-sterile and provides up to -29inHg vacuum pressure. For sterile field use, the pump is provided with sterile accessory tubing and a sterile flow control switch. The accessories are also single-use and disposable. The Quiver Aspiration Pump system is comprised of the following:

- **Quiver Aspiration Pump:** The Quiver Aspiration Pump is battery-operated (18VDC, non-rechargeable), has an ON/OFF button, and serves as a vacuum source for aspirating and suctioning for general use applications. Within the pump assembly, the DC motor drives a

diaphragm pump that provides high vacuum suction and flows in one direction for material removal only. Affixed to the pump is a waste collection bag (500mL) that collects and contains all fluids and materials that were aspirated. The aspiration pump is non-patient contacting. Sterile aspiration tubing accessories are provided with the pump to facilitate connection to other suction devices with a standard medical luer connection. The inline flow control switch allows the user to initiate and terminate the suction from the distal end of the tubing. The entire pump assembly is disposable following standard biohazard handling procedures.

- **Accessories:** Included in the pump package are the aspiration tubing and the inline control flow switch. Both accessories are individually packaged in sterile pouches. These components are finished sterile devices manufactured and sterilized by Merit Medical (South Jordan, UT) and sold to Anoxia as finished medical devices. The aspiration tubing has a standard female luer fitting. The inline flow control switch is connected to the distal end of the tubing. The tubing is 72 inches long to allow for use within a sterile field if necessary for general suction applications. The flow switch has a standard male luer that can be connected to other devices used for suction that have the same standard medical luer. The two accessories and the pump are packaged in a carton box.

5. INDICATIONS FOR USE

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

6. SUBSTANTIAL EQUIVALENCE

The Quiver Aspiration Pump is substantially equivalent to the predicate device based on the following:

Intended Use

The intended use of the proposed device is identical to that of the cleared device.

Technology

Both the Quiver Pump and Penumbra Pump perform aspiration through a single lumen aspiration tube attached to a continuous aspiration pump with a waste collection element. Any differences between the subject and predicate device were evaluated through comparative performance evaluation and design verification and validation testing which demonstrated device performance and safety. Comparative tests included Peak maximum vacuum pressure (inHg). Maximum vacuum values were obtained after stabilization of the pump was recorded. Comparative testing yielded substantially similar results.

Discussion

Based on the comparison presented in our submission, the Quiver Aspiration Pump shares the same indications for use as the Penumbra Pump MAX, as both are intended for general suction use in hospitals or clinics.

Additionally, The Quiver Aspiration Pump and Penumbra Pump MAX also share the same operating principal and have similar technological characteristics and mechanisms of action as

both serve as the source of vacuum for aspiration of materials. Both systems are provided with sterile aspiration tubing and inline flow control switch. Performance testing was completed to demonstrate safety and effectiveness of the subject device, supporting the company's substantial equivalency claim.

7. PERFORMANCE DATA

To demonstrate the substantial equivalence of the Quiver Aspiration Pump to the selected predicate device, the performance and technological characteristics were evaluated by completion of the following tests:

- Visual Inspection Test
- Leak and Vacuum Test (Air)
- Max Vacuum Test (Water)
- Simulated Use Test
- Tensile Strength Test
- System Comparative Test
- Packaging and Shelf-Life Test
- Electrical Safety and EMC Testing

8. CONCLUSION

The Quiver Aspiration Pump has the same/similar intended use, technological characteristics, and principles of operation as the predicate. Any differences between the subject and predicate devices were evaluated through design verification and validation testing and comparative testing which demonstrated device performance and safety, and do not raise any new questions of safety and effectiveness.

Based on the information submitted in this 510(k), the Quiver Aspiration Pump is substantially equivalent to the currently marketed predicate Penumbra Pump Max System.