November 23, 2022

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66 Room G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

<table>
<tr><td>RE:</td><td colspan="2">Request for pre-510(k) meeting.

We respectfully request a pre-submission meeting and request written feedback and a one hour meeting as the preferred method of feedback.</td></tr>
<tr><td>Type of Q-Sub:</td><td colspan="2">Pre-Submission meeting for a pre-510(k).</td></tr>
<tr><td>Purpose of Meeting:</td><td colspan="2">Pre-Sub to review the regulatory strategy and proposed testing.</td></tr>
<tr><td>Type of Feedback Requested:</td><td colspan="2">Meeting, 60 minutes</td></tr>
<tr><td rowspan="6">Proposed Meeting Attendees:</td><td>Name</td><td>Function</td></tr>
<tr><td>Manning Hanser</td><td>CEO</td></tr>
<tr><td>Dr. Robert Starke</td><td>CMO</td></tr>
<tr><td>Alfonso Hermida</td><td>Engineer, Tag3</td></tr>
<tr><td>Victor Gamez</td><td>Engineer, Tag3</td></tr>
<tr><td>Angela Mallery</td><td>Regulatory Consultant, NAMSA</td></tr>
<tr><td>Requested Meeting Dates:</td><td colspan="2">The preferred dates are the week of February 1st , 2023</td></tr>
<tr><td>Contact Person:</td><td colspan="2">The official contact for this pre-submission for a 510(k) is:
Angela Mallery
NAMSA, 400 US-169, Minneapolis, MN 55441
651-210-4766
amallery@namsa.com</td></tr>
<tr><td>This Pre-Submission Includes</td><td colspan="2">• Cover letter with contact information for sponsor and name of subject device
• Table of Contents
• Device Description with sufficient information to understand what the proposed device is and how it works
• Proposed intended use
• Summary of previous discussions
• An overview of the planned product development
• Specific questions for FDA feedback
• Desired method of feedback</td></tr>
</table>

If you have any questions, please contact Angela Mallery, at 651-210-4766 or amallery@namsa.com.

Sincerely,

Angela Mallery
Regulatory, NAMSA

CONTENTS

1 PURPOSE OF PRE-SUB

The purpose of this pre-sub is to introduce FDA to ALGO, and engage in a discussion on the regulatory strategy and testing to support commercialization.

2 PREVIOUS DISCUSSIONS OR SUBMISSIONS

There has been no prior formal pre-subs with FDA.

3 METHOD FOR FEEDBACK

Our preferred method of feedback is written feedback and a one-hour meeting.

4 BACKGROUND

The ALGO Clot Aspiration Pump (ALGO) was designed to act as the vacuum/aspiration pump with a small footprint, to enable physicians to extract thrombus through their choice of on label aspiration thrombectomy catheter or aspiration indicated stent retriever catheters.

No FDA guidance exists on accessories for thrombectomy devices; guidance documents do exist for Peripheral Vascular Atherectomy Devices (May 2021) and for Powered Suction Pump 510(k)s (September 1998); these two guidance documents were used in the development of the planned testing for ALGO.

Additionally, ALGO has been designed to be environmentally friendly. Currently, the housing will be sourced from recycled materials, and in the future, a clean take-apart process will liberate and separate individual components for specialty material recycling and refurbishing. A future pre-sub will be submitted to discuss the refurbishing validation process.

5 DEVICE DESCRIPTION

The ALGO Clot Aspiration Pump (ALGO) was designed to be used with third-party pump-compatible thrombectomy catheters and / or stent retrievers. The pump is designed to be sterile, single-use, battery-powered, and will be compatible with aspiration indicated catheters.

ALGO has combined the three components: (1) tubing, (2) collection canister (reservoir), and (3) aspiration pump – into one device; and has been designed to be intuitive, based on the design of other aspiration pumps; and has been designed to fit within the current workflow.

ALGO has undergone feasibility testing and are nearing design freeze, therefore some of the features, labels/terminology, and details may change between now and the 510(k) submission.

ALGO has been designed to be agnostic to a specific catheter; the software was developed based upon features of current commercially available aspiration catheters.

A simple touch screen allows for the operator/physician to be engaged with the status of the pump and choose to activate the pump in either in adaptive (APA) or continuous aspiration (STATIC) mode. The APA mode allows pressure sensor output to adjust the operation of the pump, whereas the continuous aspiration mode (STATIC) is consistent with the actions of single-mode commercially available aspiration pumps

5.1 Overview of ALGO

ALGO (Figure 1) is a sterile, single-use, pump; it includes standard nylon tubing, sealed/disposable collection canister, integrated software, and a touchscreen display.

The Touchscreen displays the battery level, Status, Mode, Duration/Time, pressure reading, and a graphical display of pressure (Figure 2); and allows the operator to select the appropriate catheter ID/Length from a drop-down menu. An example of a graphical display option of the pressure is shown in Figure 3.

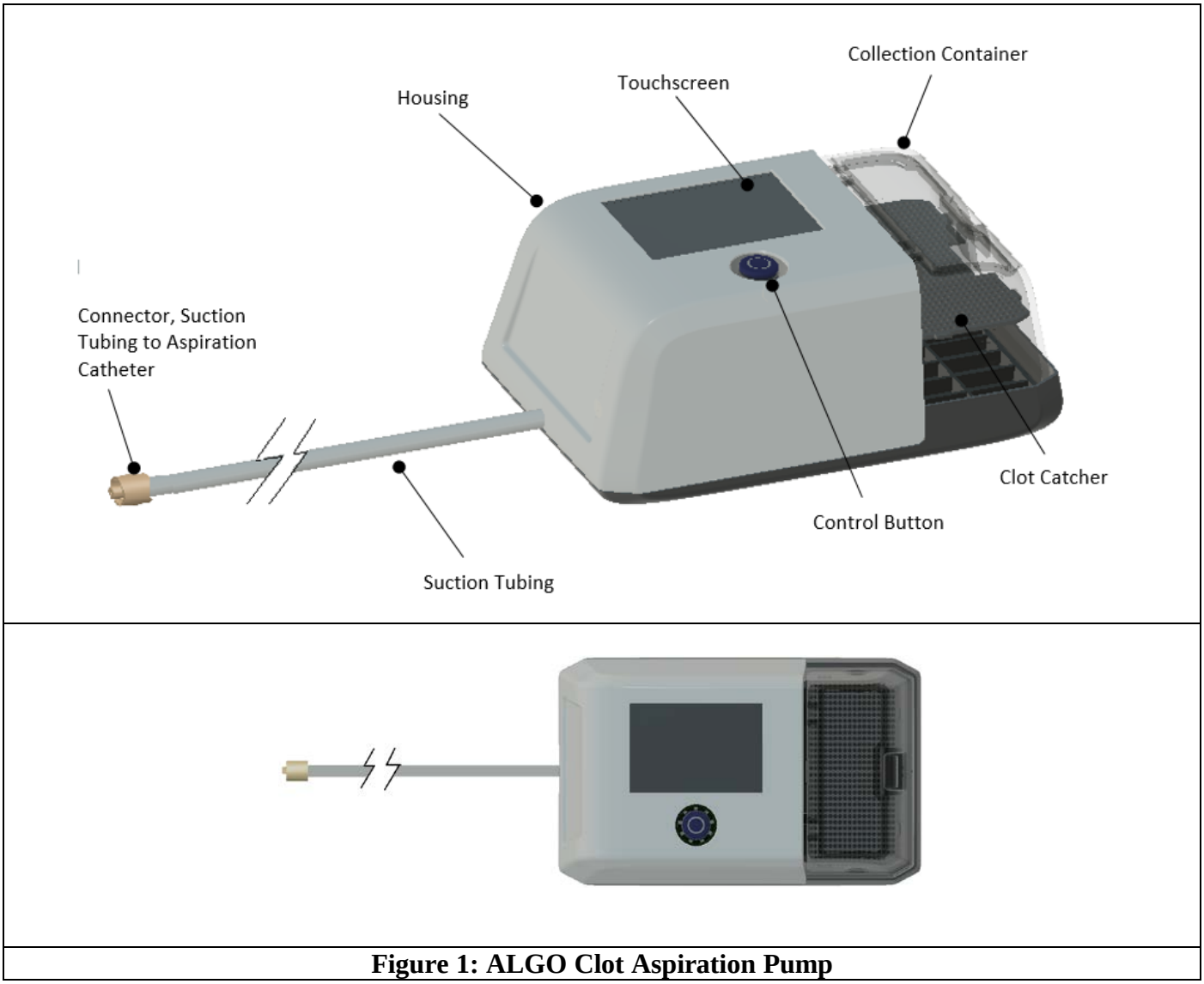


Figure 1: ALGO Clot Aspiration Pump

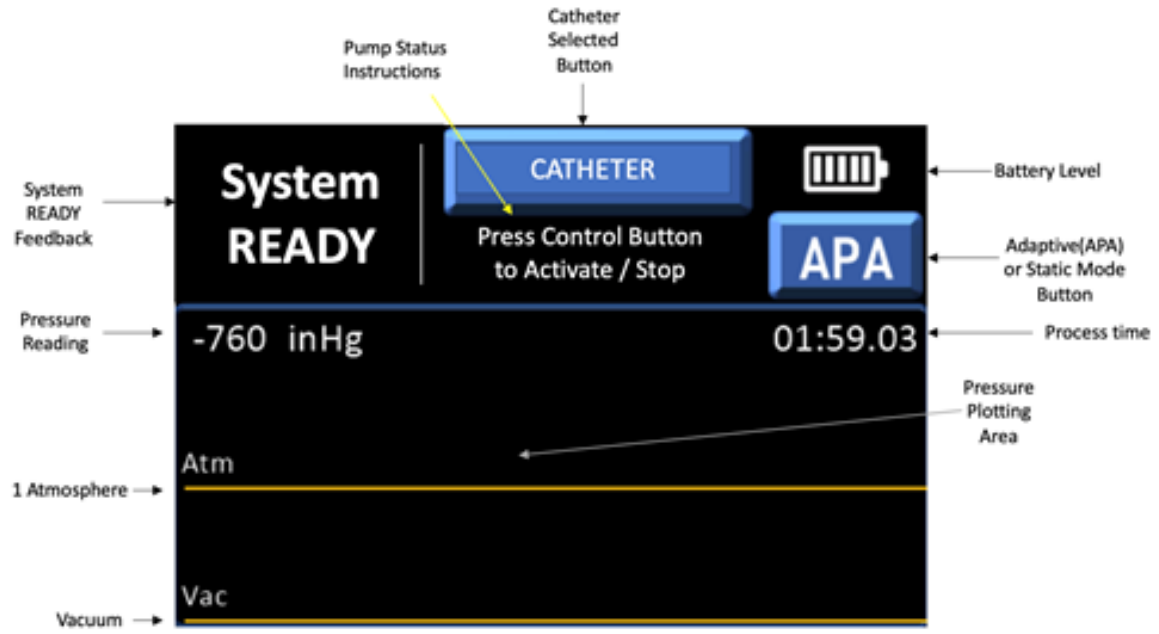


Figure 2: Touch Screen

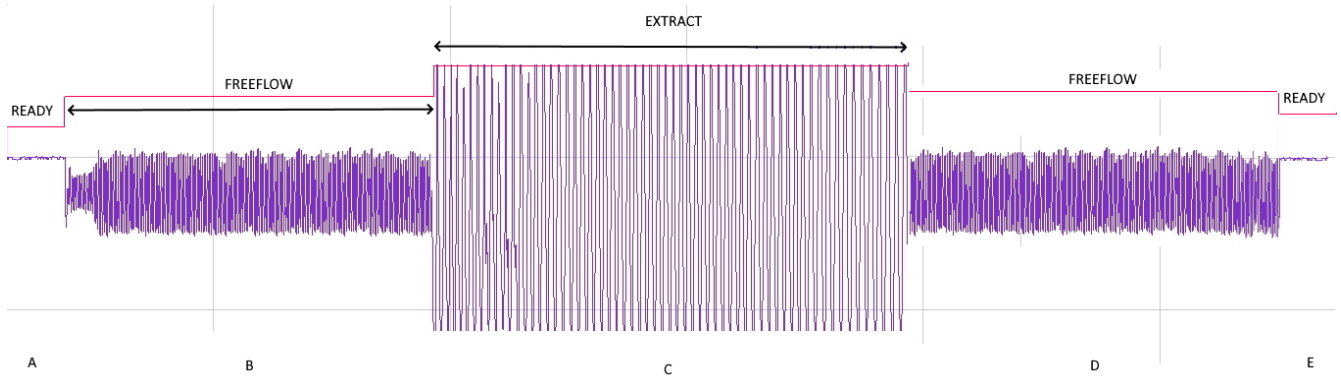


Figure 3: Graphical Representation of Pressure and Corresponding Status in APA Mode during a "typical" clot removal

5.2 Modes and Status

The ALGO is able to operate in a continuous aspiration and an adaptive mode.

The continuous aspiration mode (STATIC) is equivalent to the operation of the pumps for ZOOM; the adaptive mode (APA) allows pressure sensor output to adjust the operation of the pump, allowing non-continuous aspiration, and is equivalent to the Penumbra aspiration pumps.

The Modes and Status are not replacing or modifying the current medical practice of thrombectomy.

APA mode can be described as intermittent aspiration; with frequent varying in the amount of aspiration generated. A pressure sensor provides the information to the microprocessor, and allows the pump the ability to vary the amount of aspiration. This feature was designed to mitigate blood loss, to be able to disrupt the morphology of the thrombus, resulting in effective thrombus removal and a decrease in catheter blockage.

Table 1 lists the modes and the Pump Operational Status.

Table 2 is the description of the modes and Table 3 is the description of the status.

Table 1: Modes and Status Summary	
Mode – User Selected	**Pump Operational Status**
APA Mode	**READY** **FREEFLOW** **EXTRACTING** **OCCLUDED**
STATIC Mode	**READY** **FREEFLOW** **OCCLUDED**

Table 2: Description of Modes		
Mode	**Description**	**Parameters of Operation**
APA Mode	Uses sensor information to change the pump operation	~ 0 to -29inHg
STATIC Mode	Constant negative pressure	~ -29inHg to max pressure

Table 3: Description of Status	
Status	**Description**
READY	Pump and tubing are primed and ready
FREEFLOW	Pump and tubing operating with no blockage
EXTRACTING	When the ALGO registers a clot burden (senses a reduction in pressure), the pump switches into an operational mode allowing the pump to operate through a range of pressures pulling the clot into the catheter.
OCCLUDED	A combination of elapsed time and a reduced pressure will indicate the catheter is occluded. The pump will move into an operation mode of continuous aspiration pressure. If there is no improvement in pressure after a pre-set time, the touch screen will notify the operator the catheter is occluded (ALGO will maintain negative pressure)

5.3 Basic Operation/Flow

Figure 4: Simplified Flow Chart shows the operational steps.

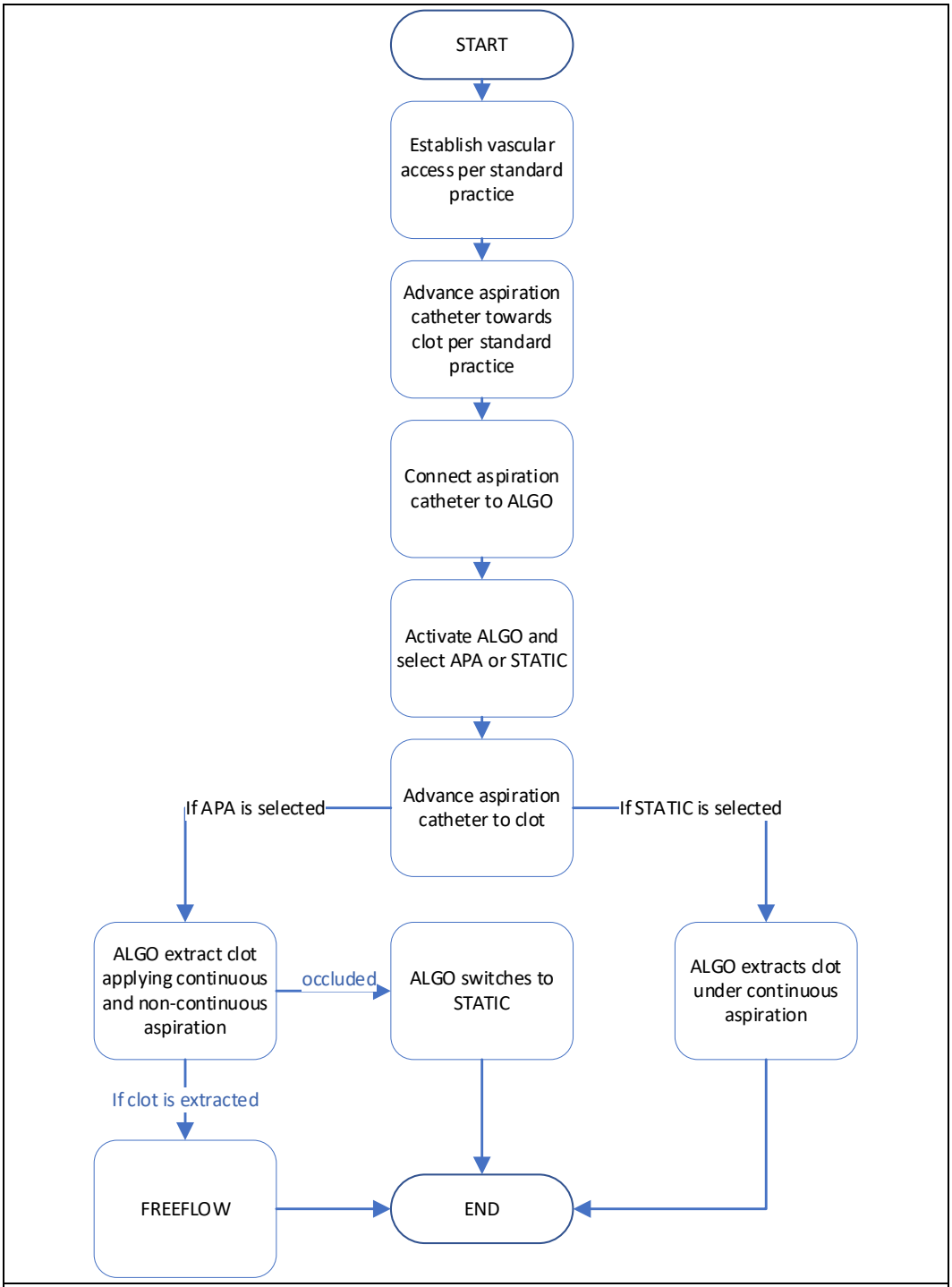


Figure 4: Simplified Flow Chart

6 PROPOSED REGULATORY STRATEGY

Currently pumps for thrombectomy are regulated as (1) General use as a powered suction pump under JCX, or (2) as part of the thrombectomy system as an aspiration pump (accessory) under the product codes related to their catheter.

We propose ALGO be classified under QEW, QEZ, and NRY because the currently cleared pumps appear location- and pump-agnostic; pumps that have been cleared as stand-alone have subsequently been used as accessories and cleared under next generation catheter 510(k)s with additional indications for use; and cleared under their parent catheter product code.

The technology of the pumps (generally) remains unchanged; the driver for new 510(k)s appears to be changes/additions to the indication for use of the aspiration catheter. Therefore, it seems appropriate that a pump for aspiration catheters should be compared to a currently cleared pump; and remain agnostic to its area of location.

We propose the following regulatory strategy (Table 4). Cardiovascular was chosen as the review panel because they are inclusive of the peripheral and cardiovascular indications; and cardiovascular will be a good place to start the conversation about regulatory path to market. We are open to suggestions and feedback on this strategy.

Table 4: Proposed Regulatory Strategy	
Target Area	Vasculature
Regulation Medical Specialty	Cardiovascular, Neurovascular
Review Panel	Cardiovascular
Product Code	QEW, QEZ, NRY
Premarket Review	Cardiovascular Devices (OHT2) Coronary and Peripheral Interventional Devices (DHT2C)
Submission Type	510(k)
Regulation Number	870.5150
Device Class	2

6.1 Proposed Indication for Use

We are developing the indication for use; Table 5 is the current working indication for use.

The indication for use has been drafted based upon the assumption ALGO will be classified under multiple product codes. We are open to suggestions and feedback on classification and predicate selection.

Table 5: Proposed Indication for Use	
Intended use	Suction device
Indication for use	The ALGO is intended for: • general suction use in hospitals or clinics • a vacuum source for aspiration catheters

See Table 6 for a summary of how pumps are currently cleared as part of cardiovascular, and neuro devices. The parameters of pumps listed as equivalent or identical, or the submission is silent about the parameters of the pump being cleared.

Table 7 compares the indication for use and overall technology of the ALGO to the predicate and reference devices.

6.2 Predicate and Reference Device Justification

The Penumbra INDIGO (K210323) was chosen as the predicate device because, common indication for use language, the Penumbra uses sensors for flow monitoring using a microprocessor with a thrombus removal

algorithm that automatically controls a valve, in the tubing to provide continuous or intermittent aspiration[1]; and the Penumbra INDIGO uses a pump initially cleared as a stand-alone (K122756). See Figure 5 for a diagram of how the Penumbra and their initial standalone pump are related.

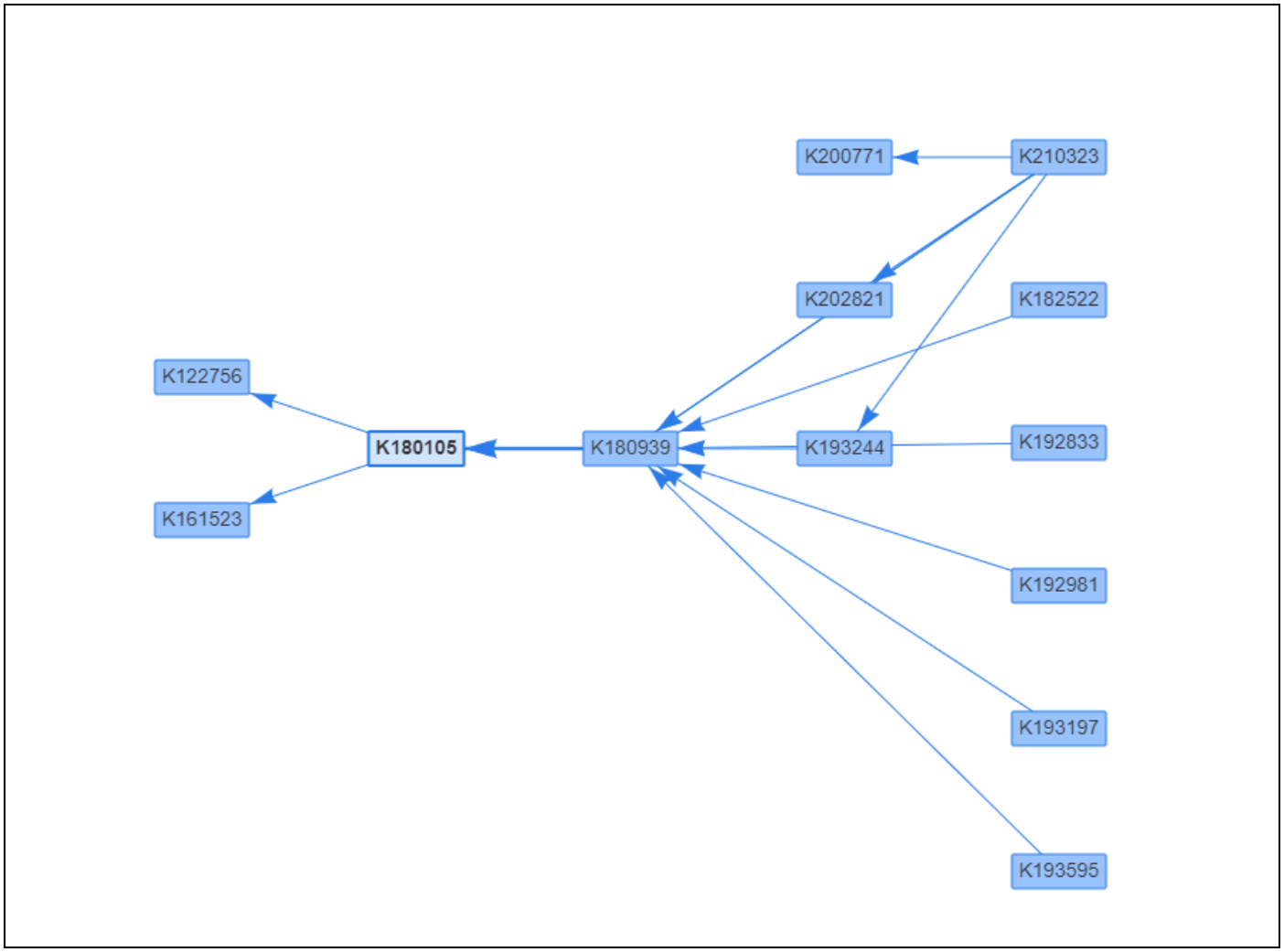
ALGO and Penumbra both have mechanisms to allow for sensors to control aspiration; ALGO is fully sterilized (Penumbra's tubing is sterile), and includes a touchscreen to control the pump (Penumbra uses a switch and audio/visual indicators). The differences in sterility and control are minor and do not raise new issues of safety or effectiveness. Bench testing will confirm the aspiration for ALGO is equivalent to Penumbra.

The ZOOM Aspiration Pump and Imperative Care System (K190105 and K210996) were chosen as references. K190105 is a stand-alone pump that was subsequently used as a predicate to subsequent submissions, and the pump is apparently unchanged during its lifecycle.

Additionally, Imperative Care, ZOOM (K210996) was listed as a reference device because the indication for allows for equivalent pumps AND the pump used in K210996 is the same pump cleared under K190105.

Although the ALGO indication for use includes a new bullet, indicating a vacuum source for aspiration catheters, this is not considered "new" or introducing new risks as the pump is used for aspiration of thrombus in subsequently cleared 510(k) with no apparent changes.

Figure 6 shows how K190105 is used to support K210996.



[1] https://www.penumbrainc.com/indigo-lightning/

Figure 5: Diagram of Penumbra K210323 submission history

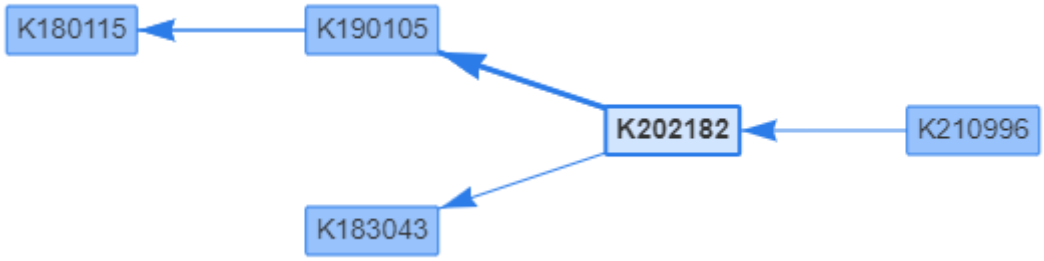


Figure 6: Diagram of K190105 and K210996 submission history

6.3 Question

See Question 1 Regulatory Strategy for the question related to the regulatory strategy.

Table 6: Overview of Pump Classifications										
Pump only clearance			**Pump initially cleared as stand alone – now part of System**				**Pump cleared as part of System**			**Stent Retriever**
(Reference) Taiwan Biomaterials ZOOM Aspiration Pump K190105	**Taiwan Biomaterials TWBM Aspiration Pump K180115**	**Penumbra Pump Max K122756**	**(Reference) Imperative Care ZOOM K211476 K210996 K202182**	**Penumbra Indigo K210083**	**Penumbra Reperfusion K211654**	**(Predicate) Penumbra Indigo K210323**	**Volcano AtheroMed Phoenix 2.4mm Atherectomy Plus System K181877**	**Volcano AtheroMed QuickClear K193197**	**Argon Cleaner K211798**	**Stryker Trevo XO K190779**
878.4780	878.4780	878.4780	870.1250	870.5150	870.1250	870.5150	870.4875	870.5150	870.5150	882.5600
Pump	Pump	Pump	Pump Canister Tubing	Catheter Separator Tubing Pump	Catheter Separator Tubing Pump	Catheter Separator Tubing Pump	Catheter Pump	Catheter Pump	Catheter Dilator Canister Pump	Catheter
Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II
JCX	JCX	JCX	NRY	QEW	NRY	QEW	MCW	QEZ	QEZ, KRA	POL, NRY
General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Neurology	Cardiovascular	Neurology	Cardiovascular	Cardiovascular	Cardiovascular	Cardiovascular	Neurology
Pump cleared as general hospital use	Pump cleared as general hospital use	Pump cleared as general hospital use	The stand alone pump now part of the system.	Same pump as other indications	Pump and tubing set cleared	Pump indicated for thrombus removal	Pump indicated for thrombus removal	Product code change from previous. Pump indicated for thrombus removal	Pump may have been cleared under K173389	510(k) summary is agnostic to parameters of pump

Table 7: Comparison Between ALGO and Similar Devices					
	Subject Device	**Predicate**	**Reference Device**		**Comparison**
	Von Medical, ALGO	**Penumbra INDIGO K210323**	**Taiwan Biomaterials, ZOOM K190105**	**Imperative Care, ZOOM K210996**	
Notes	Designed to be an equivalent aspiration pump to currently cleared pumps.	Original Pump cleared as stand alone	Original Pump cleared as stand alone	Original pump cleared as stand alone – and catheter allows use of alterative pumps	

Table 7: Comparison Between ALGO and Similar Devices					
	Subject Device	**Predicate**	**Reference Device**		**Comparison**
	Von Medical, ALGO	**Penumbra INDIGO K210323**	**Taiwan Biomaterials, ZOOM K190105**	**Imperative Care, ZOOM K210996**	
Indication for Use	The ALGO is intended for • general suction use in hospitals or clinics • a vacuum source for aspiration catheters	INDIGO Aspiration Catheters and Separators As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism INDIGO Aspiration Tubing As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump. The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	The ZOOM Canister is intended to collect aspirated fluids for disposal and prevent fluid ingress from damaging the ZOOM Aspiration Pump. The ZOOM Aspiration Tubing Set is intended to connect a suction catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow. The ZOOM Aspiration Pump is intended for general suction use in hospitals or clinics.	The ZOOM Reperfusion Catheters, with the ZOOM Aspiration Tubing and ZOOM Aspiration Pump (or equivalent vacuum pump), are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	The canister is an integral part of the device, no stand alone indication needed for the ALGO reservoir. The tubing is an integral part of the device, no stand-alone indication needed for the ALGO tubing. ALGO's indication for use for hospital use comes from ZOOM as a standalone pump. ALGO's indication for use as a vacuum source comes from the ZOOM references (which references the same pump as the predicate).
Blood Reservoir	Yes	Yes	Yes	Yes	Identical
Display of Pump operation	Yes	Yes	Yes	Yes	Identical
Nylon Tubing ID and length	0.110in 2ft minimum	0.110in[2] 8.3 ft[3]	0.110in 9-10 ft	0.110in 9-10 ft	Identical materials and ID. Substantially equivalent length: The length of the tubing is variable, ALGO is sterile allowing it in the sterile field.

[2] Identified in K193244

[3] Identified in K193244

Table 7: Comparison Between ALGO and Similar Devices					
	Subject Device	**Predicate**	**Reference Device**		**Comparison**
	Von Medical, ALGO	**Penumbra INDIGO K210323**	**Taiwan Biomaterials, ZOOM K190105**	**Imperative Care, ZOOM K210996**	
Liquid Flow Rate less than 1 LPM[4]	Yes 0 - 0.1 LPM	Yes 0 - 0.1 LPM	Not reported	Not reported	Substantially equivalent ALGO and Penumbra both have a flowrate of less than 1 LPM.
Noise level	<60dB	<60dB	<60dB	<60dB	Identical
Sensors	Yes, sensors detect pressure differences; allows to identify blood vs clot. Sensors control pump action – varying aspiration pressure.	Yes, sensors detect pressure differences; allows to identify blood vs clot. Sensors control valve action – opening and closing.	No	No	ALGO and Penumbra have pressure sensors for real-time blood flow monitoring.
Blockage Detection	Yes	Yes	No	No	Identical to Penumbra
Aspiration	Non-Continuous or Continuous Aspiration Operates continuous in blood flow and intermittent when encountering a clot.	Non-Continuous or Continuous Aspiration Operates continuous in blood flow and intermittent when encountering a clot.	Continuous Aspiration	Continuous Aspiration	Substantially equivalent All the pumps have continuous aspiration functions The ALGO and Penumbra have the ability to use non-continuous aspiration. Bench testing will confirm no additional risks are raised.
Pressure Range	~ 0 to -29inHg	0 to -29inHg[5]	0 to -29inHg	0 to -29inHg	Identical
Electrical Safety Testing	Pump will be tested to ensure compliance	Yes[6]	Yes	Yes	Identical

[4] LPM = Liters per minute

[5] Penumbra marking materials

[6] Identified in K180105

Table 7: Comparison Between ALGO and Similar Devices					
	Subject Device	**Predicate**	**Reference Device**		**Comparison**
	Von Medical, ALGO	**Penumbra INDIGO K210323**	**Taiwan Biomaterials, ZOOM K190105**	**Imperative Care, ZOOM K210996**	
Sterility	Yes – whole device	Pump = No Tubing = Yes	Pump = No Tubing = Yes	Pump = No Tubing = Yes	Substantially equivalent ALGO was designed to be near the operator, sterilization validation will be conducted. Other pumps not included here are provided sterile.

6.4 Conclusion

ALGO is an equivalent pump to the predicate; the indications for use are similar, with ALGO having a smaller indication for use in alignment with the predicate's pump, and equivalent in technology with pressure ranges, and sensor-controlled aspiration modes. Pre-clinical testing will confirm the differences are mediated; and no additional questions of safety or efficacy are introduced.

7 BENCH TESTING

Bench Testing for ALGO was based on guidance documents and 510(k) summaries for currently cleared aspiration pumps (stand-alone and cleared as part of a system).

No FDA guidance exists on accessories for thrombectomy devices; guidance documents do exist for Peripheral Vascular Atherectomy Devices (May 2021) and for Powered Suction Pump 510(k)s (September 1998); these two guidance documents were used in the development of the planned testing for ALGO.

The testing has been broken into multiple tables to address the system and components.

See 15.2 for our specific question on bench testing.

7.1 Planned Testing

The ALGO, for all intents and purposes, is equivalent to the predicate and reference pumps. The pumps function by aspirating thrombi into a collection container.

The tubing attached to the pump is industry-standard nylon tubing with a standard luer connection. The System testing demonstrates the performance of ALGO.

The following tables summarize the testing to be performed on the sterile pump/tubing, the battery and electrical testing that will be performed only on time zero units.

Table 8: ALGO Pump Testing at Time Zero	
Test Attribute	**Specification**
Battery Testing	
Compliance with ANSI/AAMI ES60601-1 and CAN/CSA C22.2 NO. 60601-1	
Compliance with IEC 60529 for IP 12	
Compliance with IEC 60601-1-2	
Compliance with ISO 10079-1	
Dimensional measurements	
Noise level	<60dB
Pressure Range	~0 to -29 inHg
Flow Rate	Less than 1 LPM

Table 9: ALGO Tubing Testing at Time Zero and at Shelf Life	
Test Attribute	**What will be tested**
Connector Compatibility	The aspiration tubing connectors shall securely connect the ALGO to the selected catheter
Tensile	Tensile strength of luer hub connector attachment to tubing.
Dimensional	ID, OD, and length will be measured
Lumen Collapse Test	The tubing lumen shall not collapse under negative pressure.

Table 10: System Testing at Time Zero and at Shelf Life	
Test Attribute	**What will be tested**
Flow Control Functionality	The flow control mechanism shall allow users to start and stop flow multiple times when the connected pump is running.
Freedom From Leakage	The pressure delivered at the tip of the aspiration tubing shall be consistent with the pressure generated by the pump.
Leak	No leaks at the catheter/tubing luer connection or at the blood reservoir.
Packaging	Visual inspections, peel strength, bubble leak tests
Transit testing	Transit testing (only at time zero)

Table 11: Equivalence Testing	
Test Attribute	**What will be tested**
Clot Removal	Tygon-type tube of varying diameters will be used to replicate representative vessel size, with an approximate 25mm thrombus. Thrombus to replicate human-organized thrombus will be manufactured from animal blood with added thrombin. Vessel sizes will be bracketed to the largest and smallest, including one in the mid-range; covering a range of catheters; and a sample of 3 per size will be tested. Tubes containing thrombus will be placed in a submerged closed saline–water bath at 37 C. A guidewire will be advanced through the simulation and across the thrombus. Each test catheter will be deployed/used according to its instructions for use. The operator will grade the amount of thrombus removed as a percent-of-total-clot-removed and the value will be recorded on the study case report. The operator will also comment on the usability of the device throughout the procedures. At the completion of each test, the clot aspirated, the clot remaining in the tube, and any distal or remaining clot materials will be photographed, assessed, observed, interpreted, and documented.

8 BIOCOMPATIBILITY

No biocompatibility testing is required.

ALGO is designed to be non-patient contacting. When used as intended, the blood that enters the tubing will not be returned to the patient. The collected blood is not intended to be returned to the patient.

9 STERILIZATION

ALGO is a sterile, single use device, with no patient contact.

ALGO will be provided sterile to SAL 10-6 using validated EO processes per the overkill method described in the recognized consensus standard ISO 11135.

10 PACKAGING

Packaging and shipping validations will be conducted to support the proposed expiration date through evaluation of the package integrity for maintaining device sterility.

11 ELECTRICAL SAFETY

EMC testing for ALGO will be tested to Electromagnetic Compatibility testing in accordance with IEC 60601-1-2 and performance bench testing in accordance with ISO 10079-1, IEC 60601-1 as well as IEC 60529 in compliance with the FDA's "Guidance Document for Powered Suction Pump 510(k)s"

12 SOFTWARE

Software testing for ALGO will be based on the FDA guidance for Peripheral Vascular Atherectomy Devices (May 2021); to represent the FDA's current interpretation of the testing of similar devices.

Software documents and reports will be included in the 510(k).

The device is not designed to connect to hospital systems or collect patient data.

13 BATTERY TESTING

Battery testing for ALGO will be based on the FDA guidance for Peripheral Vascular Atherectomy Devices (May 2021); to represent the FDA's current interpretation of the testing of similar devices.

Battery testing will include risk management, qualification testing, and performance testing considerations.

14 ANIMAL AND HUMAN CLINICAL TESTING

No animal testing or human clinical testing has been planned for ALGO.

The bench tasting will support the equivalence of the device to the predicate.

15 SPECIFIC QUESTIONS

15.1 Question 1 Regulatory Strategy

ALGO was designed as an accessory to currently cleared catheters that have been tested using a pump as the mode of aspiration; currently, there are multiple catheters that use aspiration pumps as their aspiration method (as compared with a syringe).

The path to market for these pumps has been a stand-alone clearance for general use or embedded as a component in the clearance of an aspiration catheter. See Table 5 for the proposed indication for ALGO.

The ZOOM aspiration catheters, specifically, are indicated for use "or equivalent vacuum pump" see Table 6 and Table 7).

We are proposing ALGO is a low/moderate risk device; 510(k) class II device; as currently there are many aspiration pumps currently cleared as class II devices.

As the pumps currently cleared under one classification appear to be the same pump with a new indication/classification, we are proposing multiple product codes to address the various locations of use; we are open to suggestions and feedback on the regulatory strategy, and understand these are interrelated.

- **We welcome FDA feedback on the class II 510(k) device classification, and the product code(s) to be used.**
- **Does FDA have feedback on the proposed predicate? We are open to discussions.**
- **Does FDA have feedback on the proposed indications for use?**

15.2 Question 2 Bench Testing

Bench Testing for ALGO was based upon risk, guidance documents, and 510(k) summaries for currently cleared aspiration pumps.

We have identified testing to be conducted on the pump, tubing, at a system level, and specifically of the clot model. The clot model is designed to confirm ALGO is an equivalent pump to commercially available pumps.

- **Does FDA have feedback on the proposed bench testing?**
- **Does FDA have feedback on the proposed clot model?**

15.3 Question 3 Other

The sterilization, EMC, battery testing was described in the body of the pre-sub.

The software is being developed and the 510(k) will include the elements required per the guidance and best practices; inclusive of hazard assessment, verification and validation reports.

We do not believe animal or human testing is needed to support the indication for use.

- **Does FDA have any feedback or additional considerations we have not addressed?**