SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Intragastric Balloon

Device Trade Name: Allurion™ Gastric Balloon System

Device Procode: LTI

Applicant's Name and Address: Allurion Technologies, Inc.
11 Huron Drive
Natick, MA 01760

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P250023

Date of FDA Notice of Approval: March 20, 2026

II. INDICATIONS FOR USE

The Allurion Gastric Balloon System (AGBS) is indicated to promote short-term limited weight loss in adult individuals with obesity between the ages of 22 years and 65 years with a body mass index (BMI) ≥ 30 kg/m^2 and ≤ 40 kg/m^2 who have had at least one unsuccessful attempt at a weight loss program. The residence time for each AGBS is variable with an average observed residence time of 15.3 weeks. The AGBS is to be used in conjunction with a moderate intensity lifestyle modification therapy program. The AGBS consists of up to two Allurion Balloons placed during a 10-month period.

III. CONTRAINDICATIONS

Difficulty swallowing (dysphagia):

- Any abnormal swallowing mechanism from an esophageal motility disorder such as achalasia, scleroderma, or diffuse esophageal spasm
- History of any structural esophageal abnormality such as a web, stricture, diverticulum, or para esophageal hernia

Conditions that predispose to bowel obstruction:

- History of perforated appendicitis or any other perforated abdominal viscus
- Crohn's Disease
- Severe GI motility disorder such as severe gastroparesis
- Any history of actual, or suspected, bowel obstructions or small bowel surgery
- Any history of intraperitoneal adhesions

Conditions that predispose to gastric perforation:

- History of any previous bariatric, gastric or esophageal surgery
- History of previous laparoscopic band ligation
- History of anti-reflux surgery
- Underlying thrombotic disorder

GI bleeding or conditions that predispose to GI bleeding:

- Recent history of inflammatory conditions such as esophagitis, gastritis, gastric ulceration, or duodenal ulceration
- History of vascular lesions such as esophageal varices, gastric or duodenal varices, or intestinal telangiectasias
- Benign or malignant gastrointestinal tumors
- Inability to discontinue use of non-steroidal anti- inflammatory drugs (NSAIDs) or other gastric irritants during the device period
- Patients receiving anticoagulants
- Patients receiving chronic high dose steroids
- Severe coagulopathy or any underlying thrombotic disorder
- Hepatic insufficiency or cirrhosis
- Inability or unwillingness to take prescribed proton pump inhibitor medications in preparation for and/or during device residence

Other conditions:

- Serious or uncontrolled psychiatric illness
- Diagnosed bulimia, binge eating, compulsive overeating, or similar eating-related psychological disorders
- Alcoholism or drug addiction
- Pancreatitis
- Symptomatic congestive heart failure, cardiac arrhythmia, or unstable coronary artery disease
- Pre-existing significant respiratory disease such as chronic obstructive pulmonary disease (COPD), severe sleep apnea, or cystic fibrosis
- Cancer, unless in complete remission
- Known or suspected allergies to polyurethane
- Inability or unwillingness to take prescribed antiemetic medications in preparation for and/or during device residence
- Women who are pregnant or nursing
- Placement of a new device when a gastric balloon was in the stomach less than 2 months ago
- An existing gastric balloon that is currently in the stomach

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Allurion Gastric Balloon System labeling.

V. DEVICE DESCRIPTION

The Allurion Gastric Balloon System (AGBS) is an intragastric balloon that does not require endoscopy or anesthesia for placement or removal.

The encapsulated device is swallowed and filled with approximately 550 mL of filling fluid after it reaches the stomach. The filled balloon resides in the stomach for approximately 16 weeks, then self-empties, passes through the GI tract, and is excreted.

Figure 1: The Allurion Device is a swallowed, self-emptying and naturally excreted gastric balloon. The inset shows the encapsulated Device.

A. Device Components

The Allurion Gastric Balloon System is comprised of the following components:

- The Allurion Device (Figure 2)
- The Allurion Filler Kit (Figure 4)
- The Allurion Stylet (Figure 6)
- The Allurion Practice Capsule (Figure 7)

Additionally, the Allurion Gastric Balloon System was developed for use with Merit Medical Pressure Infusor PIB500 (Class I, 510(k) exempt).

The Allurion Device and Stylet are provided non-sterile. The Allurion Filler Kit is provided sterile. All Allurion Gastric Balloon System components are labeled for single use only. The Pressure Infusor is a commercially available non-patient contacting device that may be used for multiple procedures.

Allurion Device

The Allurion Device is comprised of the following items:

- **Capsule**. The Capsule is comprised of Hydroxypropyl methylcellulose (HPMC), a vegetarian, non-animal derived, degradable material. The empty Balloon is folded and placed within the Capsule, and the Delivery Catheter passes through a prefabricated hole in the Capsule. The HPMC Capsule maintains the size and shape of the balloon and allows the patient to swallow the empty Balloon in a folded state. The HPMC Capsule is designed to degrade after it is swallowed.

- **Delivery Catheter**. The Delivery Catheter is a comprised of a barium sulfate-filled polyurethane shaft bonded to a PC connector. The distal end of the Delivery Catheter is inside the Balloon. The Delivery Catheter shaft is long enough for the connector to remain outside the patient's mouth during use. Three sets of markings on the shaft serve as reference length markings.

  The Delivery Catheter stays connected to the Balloon and is used to fill the Balloon with the Filler Kit. The barium sulfate in the shaft allows for visualization under X-ray and/or fluoroscopy to assist in locating the Balloon. After the Balloon is filled, the Delivery Catheter is detached from the Balloon by a firm tug and is discarded.

- **Balloon** (Figure 3). The Balloon is comprised of three parts: the fill valve, the release valve, and the body.

  1. **Fill Valve.** The Fill Valve is comprised of Thermoplastic Polyurethane (TPU) that is welded in manner that allows the Delivery Catheter to enter the Balloon. The Delivery Catheter is bonded to the Fill Valve. Finally, the Fill Valve is filled with an olefinic based gel.

     The Fill Valve secures the Delivery Catheter in the Balloon during use and allows the Delivery Catheter to fill the Balloon with Filling Fluid. As the Balloon fills, it expands to achieve its nominal volume. The Delivery Catheter is removed with a tug on the portion that is outside the patient's mouth. Once the Delivery Catheter is removed the gel seals the Fill Valve.

     The Balloon location can be identified at any given time during the procedure and treatment by locating the radiopaque marker inside the balloon via X-ray, ultrasound, and/or fluoroscopy.

2. **Release Valve.** The Release Valve is comprised of a barium sulfate-filled polyurethane that is mechanically sealed by a degradable monofilament (i.e. suture).

   The Release Valve suture is located inside the balloon and controls the timing of the release of the Filling Fluid. The suture located inside the balloon is exposed only to the Filling Fluid. The Filling Fluid and body temperature control the degradation of the suture. The suture degrades and allows the Filling Fluid to exit, and the balloon empties to a size that facilitates natural intestinal passage.

3. **Body.** The Balloon Body is comprised of TPU semi-ellipsoid halves. They are attached to each other by a welding process (Figure 3).

- **Female Luer Cap**. A female luer cap is provided in the Allurion Filler Kit, which may be attached to the Delivery Catheter. If after swallowing the capsule the patient is moved to the x-ray machine, the female luer cap may be used to temporarily close the delivery catheter to mitigate catheter contamination during patient transport. Once the Balloon is confirmed to be in the stomach, the female luer cap is removed and the Allurion Balloon is filled.

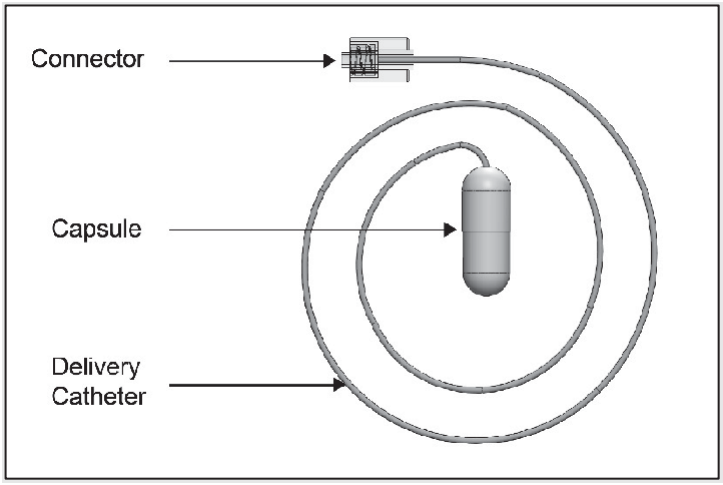

Figure 2: The Allurion Device

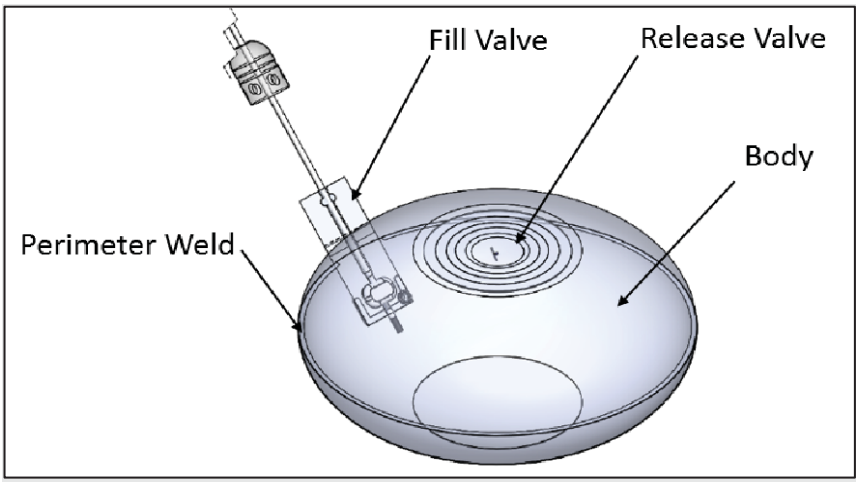

Figure 3: Allurion Balloon

Allurion Filler Kit

The Allurion Filler Kit (Figure 4) is comprised of the three items: the Filler Bag, the Extension Tube, and the Syringe. In addition, a Pressure Infusor is an accessory that is used with the Allurion Filler Kit.

- **Filler Bag.** The Filler Bag is comprised of an Ethylene-Vinyl Acetate (EVA) bladder with two ports, an injection port and a septum port. The Filler Bag has 560 mL of Filling Fluid, a custom formulated liquid containing distilled water, citric acid, and potassium sorbate. The Filler Bag was designed for use with the Merit Medical PIB500 Pressure Infusor.

  To fill the Balloon, the Filler Bag is hung inside the Pressure Infusor. The septum port connected to the bladder is pierced by the spike of the Extension Hose. The Pressure Infusor applies mechanical pressure to the Filler Bag, forcing Filling Fluid out through the pierced septum port.

- **Extension Hose.** The Extension Hose has three components, a spike and drip chamber, a tube, and a stopcock. Each component is composed of PVC except for the PE handle of the stopcock and caps.

  The spike pierces the septum of the Filler Bag septum port and seals within the port. The drip chamber shows the approximate rate of filling to give user feedback during Balloon filling. When the drip chamber displays a constant stream of Filling Fluid, the Balloon is filling as intended.

- **Syringe.** The Syringe is an off-the-shelf 30cc Syringe comprised of a PC barrel, ABS plunger, and silicone stopper. The Syringe is provided with a PP female to female luer coupler.

The Syringe may be used to remove fluid from the Balloon if the Balloon is erroneously filled in the esophagus. To perform fluid removal, the Syringe with attached coupler is connected to the Delivery Catheter connector, and the syringe is aspirated.

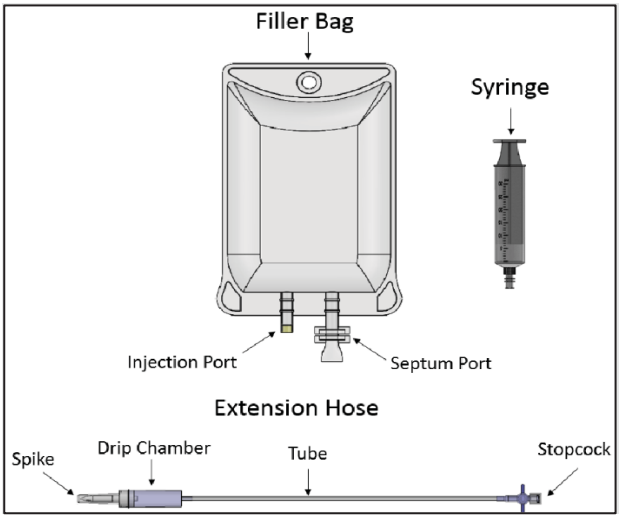

Figure 4: Allurion Filler Kit

Pressure Infusor

Pressure Infusor. The Pressure Infusor (Figure 5) is a Class 1 510(k) exempt (product code KZD) commercially available pressurization device that is placed around the Filler Bag and pressurized to fill the Allurion Device. The Pressure Infusor can be cleaned for use in multiple procedures.

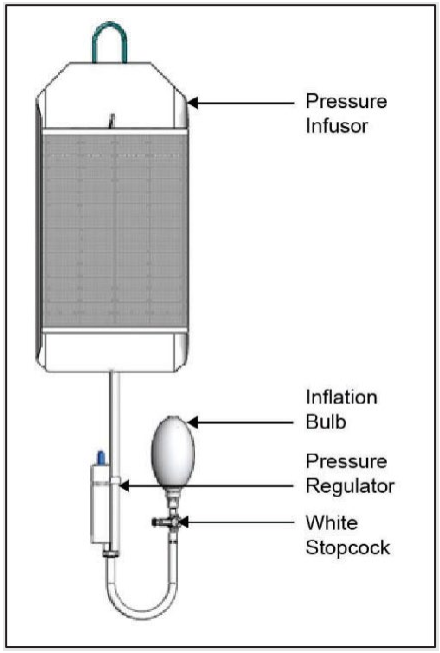

Figure 5: Pressure Infusor

Allurion Stylet

The **Allurion Stylet (**Figure 6) is comprised of a stainless-steel rod covered with PTFE and bonded to a PC connector. The distal end of the Stylet is comprised of only PTFE, which allows for flexibility of the tip (floppy tip).

The Stylet can be used to aid swallowing if a patient is unable to swallow the Device. The Stylet is inserted into the Delivery Catheter and the connector is secured with the connector of the Delivery Catheter. The Stylet stiffens the Delivery Catheter and allows the user to push the Capsule past the oropharynx into the esophagus. After the Capsule reaches the esophagus, the Stylet is disconnected from the Delivery Catheter connector and removed from the Delivery Catheter.

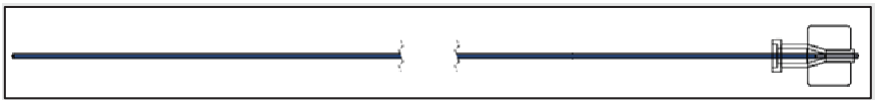

Figure 6: Allurion Stylet

Allurion Practice Capsule

The Allurion Practice Capsule is comprised of the HPMC capsule used for the Device. However, the Practice Capsule is filled with powder cellulose instead of a Balloon. The Practice Capsule approximates the size and weight of the Device Capsule and may be swallowed by the patient before the Device is administered to familiarize the patient with the swallowing experience.

Figure 7: Allurion Practice Capsule

Principles of Operation

The Allurion Device does not require endoscopy or anesthesia for placement or removal. The Device is ready to be placed via swallowing after it is removed from the packaging. If the patient is unable to swallow the Device, the Stylet can be inserted into the Delivery Catheter and used to assist patient swallowing.

Intragastric positioning of the Balloon is confirmed with fluoroscopy and/or abdominal X-ray. If after swallowing the capsule the patient is moved to the x-ray machine, a female luer cap may be used to temporarily close the Delivery Catheter to mitigate catheter contamination during patient transport. Once the Balloon is confirmed to be in the stomach, the female luer cap is removed (if used), and the Balloon is filled by the Filler Kit and Pressure Infusor. After all the Filling Fluid has emptied from the Filler Bag into the Balloon, the Delivery Catheter is removed from the Balloon. The Balloon Fill Valve seals shut during Delivery Catheter removal. The filled Balloon can be located any time during treatment by abdominal X-ray and/or fluoroscopy due to the radiopaque marker inside the balloon. In the filled state, the Balloon can also be located by ultrasound.

After approximately 16 weeks in the stomach, the Release Valve self-opens and the Balloon empties. The empty Balloon then passes through the patient's GI tract. The Allurion Gastric Balloon System consists of up to 2 Allurion Balloons used in sequence. The second Allurion Device is placed approximately 24 Weeks after the initial Allurion Device placement or two months after the initial balloon passes, whichever comes first.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of obesity (BMI > 30 kg/m^2), which can be divided into four categories: non-surgical treatments, gastric banding, bariatric surgery and intragastric balloons. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

A. Non-Surgical Treatments

Non-surgical treatments for obesity include:

- Diet, exercise, and behavioral modifications, and
- Prescription weight loss medications, such as GLP-1 receptor agonists.

B. Gastric Banding

Laparoscopic gastric banding is indicated for patients with a BMI of at least 40 kg/m^2, or a BMI of at least 30 kg/m^2 with one or more obesity-related comorbid conditions, who have failed more conservative weight reduction alternatives.

C. Bariatric Surgery

Bariatric surgery is typically recommended for patients with a BMI of at least 40 kg/m^2, or a BMI of at least 35 kg/m^2 with one or more obesity-related comorbid conditions. The most common types of bariatric surgery are described below.

- Roux-en-Y Gastric Bypass

This procedure is considered to be restrictive (a small gastric pouch restricting the amount of food consumed), as well as having a malabsorptive component (bypassing some part of the intestines). In a gastric bypass, the surgeon first constructs a proximal gastric pouch and then creates an outlet from the pouch to a limb of the small bowel. This results in a bypass of most of the stomach and duodenum.

- Vertical Sleeve Gastrectomy

Vertical sleeve gastrectomy is a restrictive procedure that reduces the size of the stomach by surgical removal of a large portion of the stomach. The open edges are then sutured together to form a sleeve. The size of the stomach is permanently reduced without bypassing the intestines or causing malabsorption.

- Biliopancreatic Diversion Duodenal Switch

The biliopancreatic diversion with duodenal switch is a procedure in which stomach removal is restricted to the outer margin, leaving a stomach sleeve with the pylorus intact. The small intestine is divided with one end attached to the stomach pouch. The majority of the small intestine is bypassed, causing nearly complete malabsorption.

D. Intragastric Balloons

Intragastric balloons are indicated for weight loss when used in conjunction with diet and exercise in patients with a BMI of 30 to 40 kg/m^2 with or without one or more obesity related comorbidities depending on the specific device. Intragastric balloons are indicated for use in adult patients who have not achieved sufficient weight loss with diet and exercise alone.

VII. MARKETING HISTORY

The Allurion Gastric Balloon System has been CE marked in Europe since 2015. It has been marketed across Europe, the Middle East, Africa, Canada, Asia and South America in the countries listed below:

- Europe: Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom (England, Wales, Scotland, Northern Ireland), Norway, Romania, Serbia, Bulgaria, Croatia, Albania
- Middle East: Saudi Arabia, Kuwait, United Arab Emirates, Qatar, Oman, Bahrain, Jordan, Iraq, Lebanon, Israel
- Africa: Egypt, Tunisia, Algeria, Morocco, Kenya, Libia
- Canada
- Asia: Vietnam, India, Hong Kong, BGA, Thailand, Indonesia, Malaysia, Singapore, Pakistan, Australia, New Zealand
- South America: Panama, Chile, Dominican Republic, Ecuador, Peru, ABC Islands, Chile, Panama, Argentina, Venezuela, Uruguay, Colombia, Costa Rica, Guatemala, Honduras, Nicaragua, El Salvador, Belize, Bahamas, Mexico, Brazil

The Allurion Device has not been withdrawn from any market due to any confirmed issues with its safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

- Insufficient or no weight loss
- Adverse health consequences resulting from weight loss
- Nausea and/or vomiting
- Chest pain, Heartburn or GERD

- Esophagitis or esophageal ulcer
- Abdominal distention with or without discomfort
- Abdominal pain
- Gastritis
- Gastric dilation
- Gastric or duodenal ulcers
- Mallory-Weiss tear
- Mucosal laceration
- GI bleeding
- Difficulty breathing
- Dehydration
- Diarrhea
- Constipation
- Fatigue
- Halitosis
- Infection
- Allergic reaction
- Adverse tissue reaction
- Pancreatitis
- Aspiration, aspiration pneumonia
- Esophageal, gastric, intestinal or other organ trauma or perforation
- Esophageal, gastric, small bowel or large bowel obstruction
- Need for endoscopic, radiologic, or surgical intervention to repair organ trauma, perforation, obstruction or other complication
- Cardiorespiratory sequelae, such as anaphylaxis, myocardial infarction (heart attack), arrhythmia, cardiac arrest, and/or bronchial obstruction and respiratory arrest
- Unintended migration of the device
- Detachment of balloon during removal, tracheal aspiration, and respiratory arrest
- Spontaneous hyperinflation of the balloon. This may be asymptomatic or symptomatic. Symptoms may include abdominal pain, abdominal distention with or without discomfort, difficulty breathing, vomiting, or may cause gastric perforation
- Death
- Vasovagal response (feeling faint, lightheaded, and/or dizzy)
- Hiccups

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

A. Laboratory Studies

The integrity and performance of the Allurion Gastric Balloon System was evaluated through the testing summarized in Table 1.

Table 1: Summary of Non-clinical Studies

Test	Purpose	Acceptance Criteria	Results
Non-clinical Performance Testing			
Device (Capsule, Balloon and Delivery Catheter)			
Capsule Volume and Mass	Test to verify the Capsule (with Balloon folded inside) meets dimensional and mass specifications	The capsule must meet the dimensions and mass requirements	Pass
Capsule Dissolution	Test to verify the Capsule remains intact long enough for a patient to swallow the device	The capsule must keep the balloon encapsulated for at least 3 minutes and 24 seconds at simulated body temperature.	Pass
Radiopaque Marker Weld Integrity	Test to verify the Delivery Catheter shaft and joints meet minimum strength requirements	The radiopaque marker must not detach under clinically relevant load	Pass
Balloon			
Material and Weld Tensile Strength	Test to verify all sections of the Balloon meet minimum tensile strength requirement	All materials and welds must meet the minimum strength requirements (tensile strength, puncture strength)	Pass
Balloon Release Valve Opening	Test to verify the Balloon release valve opens automatically within specification	The release valve must open between 90 and 140 days at simulated body temperature.	Pass
Balloon Compressibility	Test to verify the empty Balloon can transmit the gastrointestinal tract	The empty balloon must be compressible to allow for appropriate clinical use	Pass
Balloon release valve flow rate	Test to verify the Balloon release valve meets minimum flow rate specification	The release valve must have a minimum flow rate of 2.0 cc/s at simulated body temperature	Pass
Delivery Catheter			

Delivery Catheter Deflection Force	Test to verify the Delivery Catheter meets stiffness requirements	Maximum three-point bending deflection force of the delivery catheter must be between 0.40 and 1.8 N	Pass
Delivery Catheter Kink Resistance	Test to verify the Delivery Catheter maintains a minimum flow rate in a bent condition	The bend diameter at which the flow rate falls below half of the unbent flow rate must be less than 12.7 mm per EN 13868	Pass
Delivery Catheter Strength	Test to verify the Delivery Catheter shaft and joints meet minimum strength requirements	The delivery catheter must meet the minimum tensile strength requirements per BS EN ISO 20695	Pass
Delivery Catheter Pressure Test	Test to verify the Delivery Catheter resistance to liquid and air leakage	The delivery catheter must not leak when exposed to positive and negative pressure per BS EN ISO 20695 and BS EN ISO 20697	Pass
Delivery Catheter Rub Testing	Test to verify the Delivery Catheter material and markings can withstand solvents and mechanical pressure	The delivery catheter markings must not smear, lighten, or transfer when tested per ASTM F2250	Pass
Device (Capsule, Balloon and Delivery Catheter) and Allurion Filler Kit (Filler Bag, Extension Hose, Syringe)			
Simulated Deployment Testing	Test to verify the Device can be fully filled under maximum time in bench deployment	During and after simulated deployment and testing, the System must meet the following performance requirements: • Device must start filling within 15 minutes of pressurization • Balloon must be fully filled within 30 minutes • Filled balloon mass: 550 g (+15 g, -50g)	Pass

		• The Filler Kit liquid level and flow rate must be visible during filling • The balloon to delivery catheter disconnection force must be 4.1 N (+3.0 N, -2.6 N) • The fill valve must be leak free within 24 hours of delivery catheter removal The balloon cannot lose more than 2% of starting mass after cyclic simulated use	
Filler Kit (Filler Bag, Extension Hose, Syringe)			
Filler Kit Pressure Test	Test to verify the Filler Kit can withstand maximum deployment pressures post sterilization	The filler kit must not leak when pressurized to 450mmHg for 30 minutes	Pass
Filler Kit Strength	Test to verify the Filler Kit junctions meet minimum strength requirements post sterilization	All filler kit junctions must have an appropriate tensile strength per ISO 8536-4	Pass
Syringe and Delivery Catheter			
Syringe Aspiration	Test to verify the Syringe can aspirate liquid through the Delivery Catheter	The syringe must be able to aspirate 10 mL of filling fluid through the delivery catheter per BS EN ISO 20697	Pass
Stylet			
Stylet Deflection Force	Test to verify the Stylet meets the minimum stiffness requirement	Peak three-point bending deflection force of the stylet must be greater than 1.8 N	Pass
Stylet Strength	Test to verify the Stylet joints meet the minimum strength requirements	The stylet to connector must meet the minimum strength	Pass

		requirements per EN ISO 11070	
Stylet Flexing	Test to verify the Stylet is able to withstand flexing	The stylet must not fracture, loosen, or fail when tested per EN ISO 11070	Pass
Stylet Retraction from Delivery Catheter	Test to verify the stylet withdrawal from the delivery catheter does not exceed specification	The force of stylet removal from the delivery catheter must not exceed 4.9 N per EN ISO 11070	Pass
Stylet puncture	Test to verify the Stylet cannot puncture the Balloon	The stylet must not puncture the balloon film when advanced one inch into the film.	Pass

B. Additional Studies

Biocompatibility

The Allurion Gastric Balloon System was subjected to biocompatibility testing in accordance with the requirements of ISO 10993-1 and FDA CDRH's Biocompatibility guidance.

The Allurion Balloon is categorized as an intact mucosal membrane -contacting device with permanent contact duration (> 30 days). The results of biocompatibility testing for the Balloon are summarized in Table 2.

- Cytotoxicity
- Irritation
- Sensitization
- Acute systemic toxicity
- Subacute systemic toxicity
- Material-mediated pyrogen
- Genotoxicity
- Intramuscular implantation
- Chronic systemic toxicity (chemical extractable study with toxicological risk assessment)

The Delivery Catheter, Filling Fluid, and Practice Capsule are categorized as intact mucosal membrane contacting devices with limited contact duration (< 24 hours). In accordance with FDA CDRH's Biocompatibility guidance, the following biocompatibility endpoints were assessed for these device components:

- Cytotoxicity
- Irritation
- Sensitization

The Allurion Stylet contacts the interior of the Delivery Catheter, which then contacts the Filling Fluid. In accordance with FDA CDRH's Biocompatibility guidance, the following biocompatibility endpoints were assessed for this device component:

- Cytotoxicity
- Irritation
- Sensitization

The Syringe can be used to initiate Allurion Device filling contacting the filling fluid for a period of time. Therefore, in accordance with FDA CDRH's Biocompatibility guidance, the following biocompatibility endpoints were assessed for this device component:

- Cytotoxicity
- Irritation
- Sensitization

Results from the biocompatibility analyses support the biocompatibility of the Allurion Gastric Balloon System.

Cleanliness, Packaging, and Shelf Life

The Allurion Device and Stylet are supplied non-sterile, and the fluid in the Allurion Filler Kit is provided sterile. The Device, Filler Kit, and Stylet are labeled for single use only. The products are routinely monitored for bioburden levels according to ISO 11737-1 and for the absence of specific organisms. Appropriate alert and action limits for all other organisms are in place.

The Allurion Device is packaged in a thermoformed clamshell for mechanical protection inside a foil pouch with a desiccant. The Filler Bag is packaged in a nylon pouch. The entire Allurion Filler Kit is packaged in a thermoformed container for mechanical protection. The Allurion Stylet is packaged in an over tube for mechanical protection inside a Tyvek pouch.

Packaging verification was performed on each product of the Allurion Gastric Balloon System. The Allurion Device was subjected to accelerated aging for 12 months, the Filler Kit was subject to accelerated aging for 12 months, and the Allurion Stylet was subjected to accelerated aging to 24 months. All accelerated aging was performed per ASTM F1980 and were subjected to hazards of climate, dropping, stacking, low pressure, and vibration per ASTM D4169. The Device and Stylet pouches were verified per ASTM F88/F88M and ASTM F2096 or ASTM F1929. The products were evaluated to determine whether device functionality was maintained after aging and loading conditions. The shelf life and packaging testing demonstrated the packaging protects the Allurion Filler Kit, Allurion Device, and Allurion Stylet over a 12-month or 24-month shelf life.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the Allurion Gastric Balloon System for short-term limited weight loss in adult individuals with obesity between the ages of 22 years and 65 years with a body mass index (BMI) ≥ 30 kg/m^2 and ≤ 40 kg/m^2 who have had at least one unsuccessful attempt at a weight loss program in the US under IDE # G210294. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

The AllUrion Device in Adults with Clinical ObesITY (AUDACITY) study was a prospective, open-label, multi-center, randomized, two-arm, pivotal Safety and Efficacy Study of the Allurion Gastric Balloon System + Moderate Intensity Lifestyle Modification Therapy Program versus Moderate Intensity Lifestyle Modification Therapy Program for the Treatment of Adults with Obesity.

The database for this PMA reflected data collected through October 2025 and included 550 patients. There were 17 investigational sites.

The control group was concurrent with the treatment group and received no additional treatment besides nutritional guidelines, which have been shown to produce weight loss that is greater than usual care.

1. Clinical Inclusion and Exclusion Criteria
   Enrollment in the AUDACITY study was limited to patients who met the following inclusion criteria.

   a. Age ≥ 22 years and ≤ 65 years
   b. BMI ≥ 30 kg/m^2 and ≤ 40 kg/m^2
   c. Have signed study specific Informed Consent Form
   d. Willing to comply with study requirements, including follow-up visits
   e. Documented negative pregnancy test in women of childbearing potential
   f. Women of childbearing potential not intending to become pregnant for the duration of study participation. (Note: Women of childbearing potential must not be nursing at the time of treatment).
   g. Fully ambulatory without any severe chronic orthopedic disease that requires reliance on crutches, walkers or a wheelchair that could preclude exercise during the study Signed consent form.
   h. At least one unsuccessful attempt at weight loss, such as self-administered, commercial, or medically supervised lifestyle therapy program attempted within the 24 months preceding enrollment

   Patients were not permitted to enroll in the AUDACITY study if they met any of the following exclusion criteria:

a. Unable to walk 400 meters (the length of one loop of a track and field racetrack) without the use of an assistance device (e.g. cane, crutches, walker, wheelchair)
b. Symptomatic congestive heart failure, cardiac arrhythmia or unstable coronary artery disease
c. Pre-existing significant respiratory disease such as chronic obstructive pulmonary disease (COPD), severe sleep apnea and pneumonia
d. Previous bariatric surgery including adjustable gastric band and endoscopic sleeve gastroplasty, or likely to undergo bariatric surgery during the study period
e. Previous use of an intragastric gastric balloon
f. Current use of an intragastric device, Plenity and digital weight loss solutions (e.g., Noom or Calibrate)
g. History of any cancer other than non-melanoma skin cancer or papillary thyroid cancer greater than 5 years ago
h. Benign or malignant gastrointestinal tumors
i. History of chronic pancreatitis or acute pancreatitis within 12 months of enrollment
j. History of, or current, small bowel obstruction
k. History of severe GI motility disorder, such as severe gastroparesis
l. History of any esophageal, gastric, or small bowel surgery
m. History of, or current inflammatory bowel disease
n. Any history of intraperitoneal adhesions
o. Any history of open abdominal or gynecological surgery and/or radiation therapy to the abdomen, with the exception of cesarean sections performed at least 12 months prior to study enrollment.
p. History of/or signs and symptoms of/or radiographic evidence of esophageal, gastric, or duodenal disease including, but not limited to hiatal hernia 2:5cm, inflammatory diseases, varices, severe gastroparesis, recent history of gastric or duodenal ulcers, stricture/stenosis, achalasia, severe GERD requiring maximal medical therapy, or LA Grade B, C, or D esophagitis
q. Diagnosis of autoimmune connective tissue disorder (e.g., lupus, erythematous, scleroderma)
r. Immunocompromised due to medications or medical disease or diagnosed with HIV
s. History of genetic or endocrine causes of obesity not adequately controlled by medication, including hypothyroidism
t. Type 1 diabetes or Type 2 diabetes with HgbA1c 2: 7%, or treated with any anti-diabetic medications other than metformin
u. Significant acute and/or chronic infections
v. Severe coagulopathy defined as INR 1.5 or higher or platelet count <150 K/μL, hepatic insufficiency, or cirrhosis
w. Unable or unwilling to discontinue use of aspirin and/or non-steroidal anti-inflammatory agents (NSAIDs) at least 7 days prior to Allurion Deployment and continuing for 7 days after the Allurion Balloon is excreted

x. Currently taking the following medications (within 30 days prior to enrollment) and/or there is a need or anticipated need for these medications during the study:
    i. Systemic corticosteroids
    ii. Anticoagulant therapy (e.g., warfarin, dabigatran) or anti-platelet therapy
    iii. Immunosuppressive therapy (e.g., azathioprine, cyclosporine)
    iv. Narcotics, opiates, or benzodiazepines
    v. Insulin for treatment of diabetes
    vi. Anti-seizure therapy (e.g., clonazepam, phenytoin)
    vii. Anti-arrhythmics (e.g., amiodarone)
y. Inability or unwillingness to take anti-emetics during the device residence
z. Prescription or over-the- counter weight loss medication known to cause significant weight gain or weight loss within 90 days of study enrollment through study participation
aa. Uncontrolled or severe psychiatric disease other than mild depression with a patient health questionnaire score of 9 or below
bb. History of pulmonary embolism or deep venous thrombosis
cc. Has cardiac pacemaker or other electric implantable device
dd. Anemia defined as either: Hgb <11 g/dL for females, <12 g/dL for males
ee. Cessation of any nicotine products within 3 months of enrollment or plans to quit use during the study
ff. Documented total body weight loss of 2: 5% anytime 6 months preceding enrollment
gg. Residing in a location without access to study site medical resources
hh. History of or currently active eating disorders including night eating syndrome (NES), bulimia, or binge eating disorder
ii. Unwilling to refrain from any reconstructive and/or cosmetic surgery that may affect body weight during the study such as mammoplasty and lipoplasty
jj. Current, or history of illicit drug use (defined per state law) or excessive alcohol use
kk. Enrolled in another investigational study that has not completed the required primary endpoint follow-up period (Note: Subjects involved in a long-term surveillance phase of another study are eligible for enrollment in this study).
ll. Current Use (within the last month) of any smoked or non-smoked marijuana products that contain THC or unwilling to abstain from THC containing marijuana products during the trial
mm. Any conditions that, in the opinion of each site investigator, may render the subject unable to complete the study with a likely final outcome, or lead to difficulties for subject compliance with study requirements, or could confound study data.
nn. Subject is not of sufficient medical health as determined by the Investigator to participate in the study.
oo. Employees/family members of Allurion Technologies or any of its affiliates or contractors

pp. Immediate employees/family members of the Investigator, sub-Investigators, or their medical office or practice, or surgical, bariatric or hospital organizations at which study procedures may be performed
qq. An immediate family member (by marriage or blood relationship) of another subject already enrolled in the study
rr. Positive breath or stool test for H. Pylori 45.
ss. History of covid-19 with any residual symptoms
tt. Known or suspected allergies to polyurethane
uu. Uncontrolled high blood pressure defined as 2:160/100 mmHg with or without medications
vv. Uncontrolled high cholesterol or triglycerides defined as LDL 2:190 mg/dL or triglycerides 2:500 mg/dL
ww. Inability to swallow Allurion Practice Capsule

2. Follow-up Schedule

Follow-up visits for treatment and control subjects occurred according to the following schedule: visits at 1 week after implant/randomization, weeks 1, 4, 8, 12, 14, 16, 18, 20, 22, 24, 28, 32, 38, 40, 42, 44, 46, and 48. Treatment group also had a telephone follow up within 24 hours after placements and an additional follow-up at Week 25. A summary of required visits and procedures is shown in Table 2 and 3.

Table 2: Schedule of Assessments AGBS + Moderate Intensity Lifestyle Therapy Group

Procedures	SV	BV	Day 0	Tel Call	W1	W4	W8	W12	W14	W16	W18	W20	W22	W24	Tel Call[7]	W25[7]	W28	W32	W36	W38	W40	W42	W44	W46	W48
Window[6]	*	**		w/in 24 hrs	± 3d	± 7d	± 7d	± 7d	± 7d	± 7d	± 7d	± 7d	± 7d	± 7d	w/in 24 hrs	7d post Wk 24 ± 3d	28d post Wk 24 ± 7d	56d post Wk 24 ± 7d	84d post Wk 24 ± 7d	98d post Wk 24 ± 7d	112d post Wk 24 ± 7d	126d post Wk 24 ± 7d	140d post Wk 24 ± 7d	154d post Wk 24 ± 7d	168d post Wk 24 ± 7d
Informed Consent	X																								
Inclusion/Exclusion Criteria	X																								
AE/ConMeds	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Proton Pump Inhibitor[4]		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
AGBS Deployment			X											X[7]											
Randomization[5]		X																							
Medical & Obesity History, physical, height	X																								
Vital Signs	X		X		X									X		X									X
Weight	X	X	X		X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X
H Pylori	X																								
ECG	X																								
Pregnancy Test[3]	X		X											X[7]											
Blood Tests	X																								X
Practice Capsule	X																								
Questionnaires: PHQ-9	X																								
Questionnaire: IWQOL		X												X											X
Questionnaire: Rhodes Index		X	X	X	X									X[7]	X	X									
Questionnaire: TFEQ		X					X											X							
Questionnaire: Abdominal Pain VAS					X											X									
Barium Swallow	X																								
Ultrasound Abdominal						X[8]	X[8]	X[8]	X[8]	X[8]	X[8]	X[8]	X[8]	X[8]			X[4,7]	X[4,7]	X[4,7]	X[4,7]	X[4,7]	X[4,7]	X[4,7]	X[4,7]	X[7]
Xray or Fluoroscopy			X											X[7]											

Procedures	SV	BV	Day 0	Tel Call	W1	W4	W8	W12	W14	W16	W18	W20	W22	W24	Tel Call[7]	W25[7]	W28	W32	W36	W38	W40	W42	W44	W46	W48
Window[6]	*	**		w/in 24 hrs	± 3d	± 7d	± 7d	± 7d	± 7d	± 7d	± 7d	± 7d	± 7d	± 7d	w/in 24 hrs	7d post Wk 24 ± 3d	28d post Wk 24 ± 7d	56d post Wk 24 ± 7d	84d post Wk 24 ± 7d	98d post Wk 24 ± 7d	112d post Wk 24 ± 7d	126d post Wk 24 ± 7d	140d post Wk 24 ± 7d	154d post Wk 24 ± 7d	168d post Wk 24 ± 7d
Moderate Intensity Lifestyle Therapy			X[5]		X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	
Protocol Deviations	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

*≤60 days pre-baseline
**21-8 days prior to Day 0
[1]Subject must take proton pump inhibitor for 7 days prior to Day 0
[2]Randomization can be performed up to 7 days prior to Day 0
[3]Only required for female subjects of childbearing potential
[4]The second Allurion Balloon must not be placed until confirmation that the first Balloon is no longer present in the stomach or the GI tract, See sections 7.22 and 7.23. Once it has been determined the balloon has been excreted, these evaluations will no longer be required.
[5]Moderate Intensity Lifestyle Therapy can be performed within 24 hours of the Day 0 visit to maintain the blind of the RDN
[6]The schedule/windows for Week 25 through Week 48 Visits are based off the actual date of the Week 24 Visit (date 2nd balloon was placed).
[7]Rhodes Index and pregnancy test at Week 24, telephone call within 24 hours of Week 24, Week 25, and imaging (Weeks 28 through 48) are not required if the subject does not undergo a second balloon placement.

Table 3: Moderate Intensity Lifestyle Therapy (MILMTP) Control Group

Procedures	SV	BV	Day 0	W1	W4	W8	W12	W14	W16	W18	W20	W22	W24	W28	W32	W36	W38	W40	W42	W44	W46	W48
Window[8]	*	**		+ 3d	+ 7d	+ 7d	+ 7d	+ 7d	+ 7d	+ 7d	+ 7d	+ 7d	+ 7d	28d post Wk 24 ± 7d	56d post Wk 24 ± 7d	84d post Wk 24 ± 7d	98d post Wk 24 ± 7d	112d post Wk 24 ± 7d	126d post Wk 24 ± 7d	140d post Wk 24 ± 7d	154d post Wk 24 ± 7d	168d post Wk 24 ± 7d
Informed Consent	X																					
Inclusion/Exclusion Criteria	X																					
AE/ConMeds	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Proton Pump Inhibitor[1]		X																				
Randomization[2]		X																				
Medical & Obesity History, physical, height	X																					
Vital Signs	X		X	X									X									X
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
H Pylori	X																					
ECG	X																					
Pregnancy Test[3]	X																					
Blood Tests	X																					X
Practice Capsule	X																					
Questionnaires: PHQ-9	X																					
Questionnaire: IWQOL		X											X									X
Questionnaire: TFEQ		X				X									X							
Barium Swallow	X																					
Moderate Intensity Lifestyle Therapy			X[4]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Protocol Deviations	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

*≤60 days pre-baseline
**21-8 days prior to Day 0
[1]Subject must take proton pump inhibitor for 7 days prior to Day 0
[2]Randomization can be performed up to 7 days prior to Day 0
[3]Only required for female subjects of childbearing potential
[4]Moderate Intensity Lifestyle Therapy can be performed within 24 hours of the Day 0 visit to maintain the blind of the RDN
[8]The schedule/windows for Week 28 through Week 48 Visits are based off the actual date of the Week 24 Visit (date weight is measured).

The treatment group received a second Balloon at the week 24 visit and were followed through to week 48. Prior to placing the second Allurion Balloon, the first Balloon was confirmed to have exited the body. If the first balloon was still present, ultrasound evaluations were conducted every 2 weeks until the Balloon exited. The second Balloon was placed 2 weeks later. Adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints

With regards to safety, the primary safety endpoint is the overall incidence of procedure or device-related Serious Adverse Events through 48 weeks.

With regards to effectiveness, the pivotal trial has two co-primary effectiveness endpoints:

- Co-Primary Effectiveness Endpoint 1: Treatment Group Responder Rate (RR) dichotomized at 5% Total Body Weight Loss (TBWL) at 48 weeks is significantly greater than 50%.
- Co-Primary Effectiveness Endpoint 2: Treatment Group mean %TBWL is significantly greater than Control Group mean %TBWL at 48 weeks, with a super superiority margin of 3.0%.

B. Accountability of PMA Cohort

The 550 randomized subjects comprise the Intention-to-Treat (ITT) population. Of these 550 subjects, 527 subjects (264 AGBS; 263 Control) comprise the Safety Population, having completed a Day 0 visit. Twenty-three subjects (11 AGBS; 12 Control) exited from the study post-randomization, but prior to Day 0, due to reasons such as use of prohibited medications, inability to meet study follow-up requirements, elevated blood pressure leading to exclusion, and undisclosed personal reasons per the patient. These patients were excluded from the safety population.

The primary population for the effectiveness analyses is the Modified Intention-to-Treat (mITT) population, which excludes any subject who was unable to swallow the Allurion device or any subject who was not able to start the MILMTP on Day 0.

Three subjects failed to swallow the AGBS capsule on Day 0 and were excluded from the mITT population, leading to an mITT population of 524 subjects (261 AGBS; 263 Control).

The mITT population is the population for determination of benefit. Eleven out of 14 subjects excluded in the mITT population withdrew consent prior to attempting to swallow an Allurion device and only 3 subjects were not able to swallow the device and therefore did not start their assigned therapy.

Of the 397 subjects in both groups who completed through week 24, 367 completed the study through week 48. One hundred and eighty-five AGBS subjects successfully received Allurion Balloon 2, representing 70.9% (185/261) of those receiving Allurion Balloon.

See Figure 8 for the subject accountability flowchart.

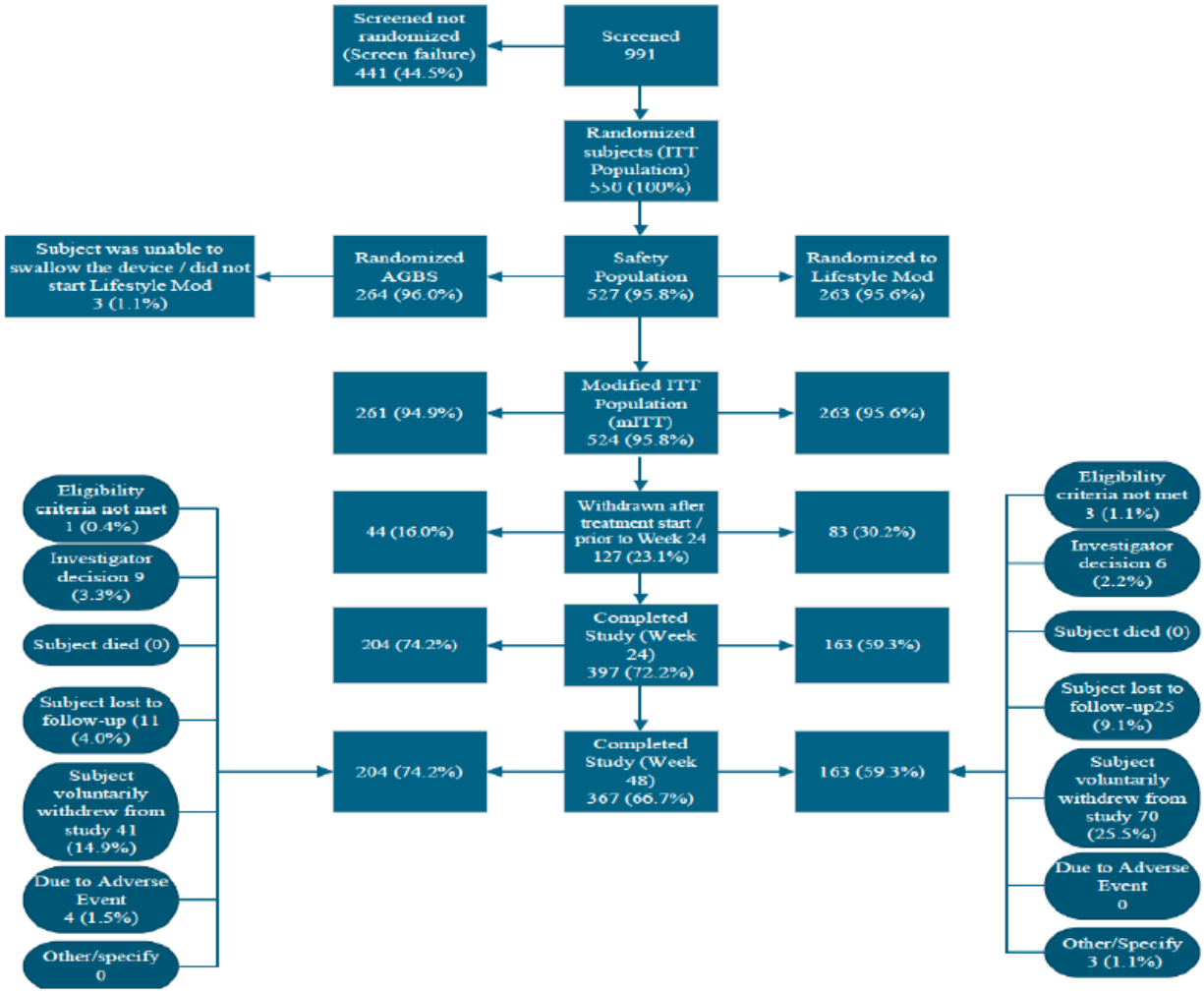

Figure 8: Subject Accountability Flowchart

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an obesity study performed in the US. A summary of the subject demographics for all screened subjects and in the mITT population is provided in Table 4. There were no significant differences in age, gender, race or ethnicity between the AGBS group and the Control group in either of the analysis populations. Additionally, height and baseline weight and BMI are similar between the treatment groups.

Table 4: Baseline Demographics and Characteristics (mITT Population)

	Total Subjects (N=524)	Randomized to AGBS (N=261)	Randomized to Control (N=263)	P-values
Age				0.4699
N	524	261	263	
Mean	42.9	43.1	42.6	
SD	8.56	8.51	8.62	
Min, Max	22, 63	25, 59	22, 63	
Age, n (%)				1.0000
< 50 Years	386 (73.7)	192 (73.6)	194 (73.8)	
>= 50 Years	138 (26.3)	69 (26.4)	69 (26.2)	
Sex at birth, n (%)				1.0000
Male	46 (8.8)	23 (8.8)	23 (8.7)	
Female	478 (91.2)	238 (91.2)	240 (91.3)	
Race, n (%)				
American Indian or Alaska Native	2 (0.4)	1 (0.4)	1 (0.4)	
Asian	8 (1.5)	7 (2.7)	1 (0.4)	
Black or African American	61 (11.6)	31 (11.9)	30 (11.4)	
Native Hawaiian or Pacific Islander	2 (0.4)	1 (0.4)	1 (0.4)	
White (Caucasian)	396 (75.6)	193 (73.9)	203 (77.2)	
Multiracial	7 (1.3)	4 (1.5)	3 (1.1)	
Not disclosed	2 (0.4)	1 (0.4)	1 (0.4)	
Other	46 (8.8)	23 (8.8)	23 (8.7)	
Ethnicity, n (%)				0.3645
Hispanic or Latino	131 (25.0)	70 (26.8)	61 (23.2)	
Not Hispanic or Latino	393 (75.0)	191 (73.2)	202 (76.8)	
Weight (lbs)				0.9087
N	524	261	263	
Mean	216.51	216.64	216.38	
SD	26.248	25.994	26.545	
Min, Max	156.0, 293.4	156.0, 293.4	159.5, 291.6	
BMI				0.7941
N	524	261	263	
Mean	35.55	35.58	35.52	
SD	2.758	2.772	2.749	
Min, Max	29.4, 41.4	29.6, 40.6	29.4, 41.4	

D. Safety and Effectiveness Results

1. Safety Results

   The analysis of safety was based on the 527 randomized subjects: 264 treated subjects and 263 control subjects available for the 48-week evaluation. Adverse effects are reported in Tables 5 to 8.

   Adverse effects that occurred in the PMA clinical study:

   The adverse events observed in the AUDACITY Study were typical of those associated with gastric balloons, including nausea, abdominal pain, and vomiting (Table 5). There were no subject deaths in the trial. The types and severity of non-serious adverse events, including device-related adverse events, are similar to other commercially available, liquid-filled intragastric balloons, although the rates may be lower than other non-adjustable liquid-filled balloons.

Table 5: Summary of All Adverse Events (Safety Population)

	Total Subjects (n=527)		AGBS Subjects (n=264)		Control Subjects (n=263)	
	Number of Events	Number (%) Subjects	Number of Events	Number (%) Subjects	Number of Events	Number (%) Subjects
Adverse Events (AEs)	**2619**	**408 (77.4%)**	**2221**	**261 (98.9%)**	**398**	**147 (55.9%)**
Procedure- or Device-related AEs	**1652**	**259 (49.1%)**	**1652**	**259 (98.1%)**	**0**	**0**
Procedure-related AEs	41	33 (6.3%)	41	33 (12.5%)	0	0
Device-related AEs	1611	259 (49.1%)	1611	259 (98.1%)	0	0
Unanticipated AEs	**11**	**8 (1.5%)**	**11**	**8 (3.0%)**	**0**	**0**

a) Serious Adverse Events

Except for AEs related to GI disorders and fatigue, the AE profiles were similar in the AGBS and Control groups. Most AEs in the AGBS Group were mild or moderate (97%), indicating that the AGBS was well-tolerated by subjects (Table 6).

Table 6: Severity of Adverse Events (Safety Population)

	Total Subjects (n=527)		AGBS Subjects (n=264)		Control Subjects (n=263)	
	Number (%) Events	Number (%) Subjects	Number (%) Events	Number (%) Subjects	Number (%) Events	Number (%) Subjects
Adverse Events (AEs)	2619	408 (77.4)	2221	261 (98.9)	398	147 (55.9)
Mild AEs	1982 (75.7)	380 (72.1)	1696 (76.4)	260 (98.5)	286 (71.9)	120 (45.6)
Moderate AEs	565 (21.6)	211 (40.0)	459 (20.7)	144 (54.5)	106 (26.6)	67 (25.5)
Severe AEs	49 (1.9)	33 (6.3)	46 (2.1)	30 (11.4)	3 (0.8)	3 (1.1)
Unknown Severity	23 (0.9)	14 (2.7)	20 (0.9)	11 (4.2)	3 (0.8)	3 (1.1)

A total of 21 serious adverse events (SAEs) were reported (18 in AGBS Group and 3 in Control Group) in 13 subjects (10 in AGBS Group and 3 in Control Group).

The three SAEs reported in the Control Group were bone fracture, ovarian torsion, and appendicitis. Two SAEs in the AGBS Group were not related to the device or the procedure: breast cancer, bulging disk.

Of the 18 SAEs reported in the AGBS Group, 15 were device-related and occurred in 8 subjects after placement of Allurion Balloon #2 (Table 7). There were no SAEs reported for Allurion Balloon #1. In one subject, gastric perforation with necrosis in the stomach and small bowel was observed one day after placement of Allurion Balloon #2. Imaging demonstrated occlusion of the left gastric artery and additional necrotic regions were identified in areas not in contact with the balloon. The root cause analysis concluded that an underlying coagulopathy causing thrombosis, ischemia, and multifocal necrosis was the most likely etiology, predisposing the patient to gastric wall weakening and perforation.

The three SAEs reported in the Control Group were bone fracture, ovarian torsion, and appendicitis. Two SAEs in the AGBS Group were not related to the device or the procedure: breast cancer, bulging disk.

Table 7: Device- or Procedure- related SAEs by MedDRA term (Site-reported) (Safety Population)

	AGBS (N=264) Number (%) Subjects, Number Events	
System Organ Class / Preferred Term	**Device-Related**	**Procedure-Related**
Gastrointestinal disorders	**8 (3.0), 13**	**0, 0**
Gastric perforation	1 (0.4), 1	0, 0
Gastric ulcer	1 (0.4), 1	0, 0
Haematemesis	1 (0.4), 1	0, 0
Nausea	3 (1.1), 3	0, 0
Obstruction gastric	3 (1.1), 3	0, 0
Vomiting	4 (1.5), 4	0, 0
Metabolism and nutrition disorders	**1 (0.4), 1**	**0, 0**
Metabolic alkalosis	1 (0.4), 1	0, 0
Renal and urinary disorders	**1 (0.4), 1**	**0, 0**
Acute kidney injury	1 (0.4), 1	0, 0

b) Unanticipated Adverse Device Effects

There were 11 Unanticipated AEs (UAEs) in the AGBS Group: one occurrence of a vasovagal event and 10 occurrences of hiccups in a total of eight subjects. The vasovagal event occurred during balloon placement. Before the balloon was completely filled, the patient developed pre-syncopal symptoms (nausea, lightheadedness). The fill was stopped with only 25 cc of fluid in the filler bag remaining, and the catheter was removed. The patient was moved from the chair to a stretcher and vitals were taken. The initial HR was 54 and BP 119/72. The patient's condition continued to improve with HR increasing into the 70's. The patient sat up and the next blood pressure on sitting was 131/100 with heart rate 71-73. The patient's symptoms completely resolved, and a final x-ray image was obtained demonstrating successful balloon administration. All episodes of hiccups were reported as mild and resolved completely.

c) Display of Adverse Events

It is important to understand the nature, frequency and duration of adverse events that occurred in the study. Although the total number of adverse events in the study is high, this is a phenomenon seen in all liquid filled balloon studies. Nausea and vomiting are almost universal in all subjects receiving a liquid filled balloon due to the accommodation of the stomach to the balloon in the first few days. Most of these mild to moderate symptoms such as nausea, vomiting and abdominal pain resolve following this accommodation period.

Occasionally, there may be recurrence of intermittent nausea or vomiting during the course of the balloon residence on account of advancing or changing the diet. Table 8 displays the more common reported Gastrointestinal AEs.

Table 8: Gastrointestinal Adverse Events by Treatment Group (Safety Population)

	Total Number (%) Subjects, Number Events		AGBS (N=264) Number (%) Subjects, Number Events	
System Organ Class / Preferred Term	AGBS (N=264)	Control (N=263)	Device-Related	Procedure-Related
Gastrointestinal disorders	260 (98.5), 1725	42 (16.0), 67	259 (98.1), 1525	20 (7.6), 28
Abdominal discomfort	39 (14.8), 43	1 (0.4), 1	39 (14.8), 42	0, 0
Abdominal distension	43 (16.3), 49	0, 0	40 (15.2), 46	0, 0
Abdominal pain	204 (77.3), 372	1 (0.4), 1	203 (76.9), 354	4 (1.5), 4
Abdominal pain upper	11 (4.2), 12	2 (0.8), 2	11 (4.2), 11	0, 0
Constipation	73 (27.7), 86	9 (3.4), 12	50 (18.9), 55	0, 0
Diarrhea	71 (26.9), 95	14 (5.3), 14	39 (14.8), 47	3 (1.1), 3
Dyspepsia	56 (21.2), 68	2 (0.8), 2	52 (19.7), 60	0, 0
Eructation	48 (18.2), 58	1 (0.4), 1	1 (0.4), 1	0, 0
Flatulence	18 (6.8), 21	0, 0	18 (6.8), 20	0, 0
Gastric perforation	1 (0.4), 1	0, 0	1 (0.4), 1	0, 0
Gastric ulcer	1 (0.4), 1	0, 0	1 (0.4), 1	0, 0
Gastritis	2 (0.8), 2	0, 0	0, 0	0, 0
Gastrooesophageal reflux disease	34 (12.9), 37	2 (0.8), 2	31 (11.7), 33	1 (0.4), 1
Nausea	253 (95.8), 502	10 (3.8), 10	250 (94.7), 46	9 (3.4), 9
Retching	97 (36.7), 128	0, 0	94 (35.6), 122	5 (1.9), 5
Vomiting	142 (53.8), 211	9 (3.4), 9	135 (51.1), 191	6 (2.3), 6

2. Effectiveness Results

Co-Primary Effectiveness Endpoint #1 for the AUDACITY Study was defined as: Treatment Group Responder Rate (RR) dichotomized at 5% TBWL at 48 weeks is significantly greater than 50%.

In the mITT population using the pre-specified multiple imputation method identified in the Statistical Analysis Plan, *Co-Primary Effectiveness Endpoint #1 was met, with 58.0% (95% CI: 51.2% to 64.9%; p-value = 0.0102) of AGBS subjects having 5% TBWL or greater at 48 weeks.* Results for the mITT, ITT, and PP populations using various methods of imputation are summarized in Table 9.

Table 9: Co-Primary Effectiveness Endpoint #1 Results

Population	AGBS Group (95% CI) Multiple Imputation	AGBS Group (95% CI) LOCF
mITT	58.0% (51.2, 64.9) p=0.0102	54.0% (47.8, 60.2) p=0.0968
ITT	58.4% (51.7, 65.1) p=0.0068	51.3% (45.2, 57.3) p=0.3365
PP	57.2% (49.3, 65.1) p=0.0363	56.7% (48.6, 64.6) p=0.0469

Co-Primary Effectiveness Endpoint #2 for the AUDACITY Study was defined as: Treatment Group mean %TBWL is significantly greater than Control Group mean %TBWL at 48 weeks, with a super superiority margin of 3.0%.

For Co-Primary Effectiveness Endpoint #2, using the MMRM method, the difference between the two groups at 48 weeks was 3.05% (95% CI: 2.09, 4.00). Using the LOCF method, the difference between the two groups at 48 weeks was 3.77% (95% CI: 2.69, 4.86) (Table 10). Using MMRM, the super-superiority margin was 2.09%. *Co-primary effectiveness endpoint #2 was not met for the mITT population at 48 weeks.* While this did not meet the super superiority margin of 3.0%, the difference in weight loss was clinically meaningful. Results for the ITT and PP populations are also provided in Table 10.

Table 10: Co-Primary Effectiveness Endpoint #2 Results

Population	Imputation Method	AGBS Group Mean %TBWL (95% CI)	Control Group Mean %TBWL (95% CI)	Difference (AGBS-Control) (95% CI)	p-value
mITT	MMRM	7.15 (6.50, 7.79)	4.10 (3.39, 4.81)	3.05 (2.09, 4.00)	0.4632
	MI	7.39 (6.44, 8.34)	4.30 (3.24, 5.36)	3.09 (1.68, 4.51)	0.4478
	LR/LOCF	6.86 (6.10, 7.63)	3.09 (2.32, 3.86)	3.77 (2.69, 4.86)	0.0805
ITT	MMRM	7.15 (6.50,7.79)	4.10 (3.39, 4.81)	3.05 (2.09, 4.00)	0.4632
	MI	7.46 (6.48, 8.44)	4.31 (3.28, 5.34)	3.16 (1.68, 4.63)	0.4181
	LR/LOCF	6.51 (5.77, 7.26)	2.95 (2.21, 3.70)	3.56 (2.51, 4.61)	0.1479
PP	MMRM	7.43 (6.62, 8.23)	4.13 (3.36, 4.90)	3.29 (2.18, 4.41)	0.303
	MI	7.40 (6.30, 8.49)	4.33 (3.26, 5.40)	3.07 (1.54, 4.59)	0.4666
	LR/LOCF	7.44 (6.37, 8.51)	4.09 (3.09, 5.10)	3.35 (1.88, 4.82)	0.319

3. Exploratory Analyses

a) 24- and 40-Week Results

In the mITT population using MI at 24 weeks, 58.5% (95% CI: 52.2%, 65.1%) of AGBS subjects were responders.

Evaluating the AGBS endpoints at Week 40 offers important insight into its effectiveness after treatment. This analysis assesses endpoints at the time of excretion of Allurion Balloon #2, aligning with other intragastric balloon studies where primary endpoints were evaluated at the time of device removal.
At Week 40, using LOCF in the mITT population, the mean weight loss in the AGBS group was 7.38% vs. 3.16% in the Control Group; the mean between-

group difference was 4.22% (95% CI: 3.18, 5.26). The percent of responders at week 40 using MI was 63.9% (95% CI: 57.5%, 70.3%).

b) Responder Rate Analyses

Super-responders were also evaluated. In the mITT population using MI, 25.4% of subjects (95% CI: 19.7, 31.1) and 32.1% of subjects (95% CI: 25.8, 38.5) had greater than or equal to 10% TBWL at 24 weeks and 48 weeks, respectively.

The benefit of receiving two balloons was also evaluated. In subjects receiving two balloons (n=185), 58.4% of subjects (95% CI: 51.2, 65.7) had greater than or equal to 5% TBWL at 48 weeks.

c) Subgroup Analyses

Both co-primary effectiveness endpoints were evaluated across age, sex, race, BMI, and ethnicity. Results are shown in Figure 9 and Figure 10.

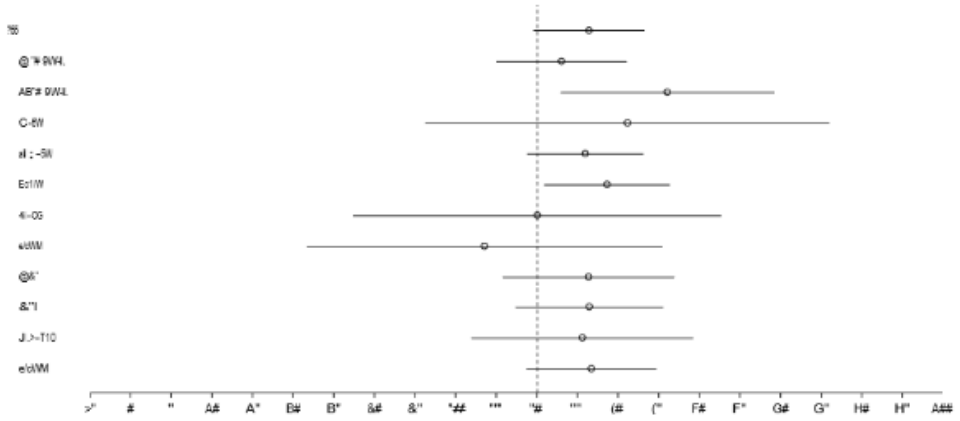

Figure 9: Forest plots for co-primary effectiveness endpoint #1

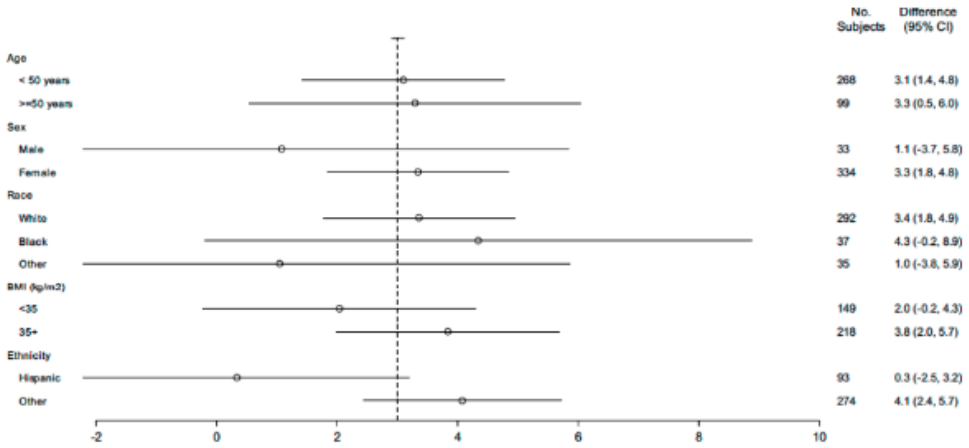

Figure 10: Forest plots for co-primary effectiveness endpoint #2

4. Pediatric Extrapolation
   In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 17 principal investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

The Allurion Gastric Balloon has been approved in 78 countries since 2015. As of December 31, 2025, more than 204,000 devices have been distributed to countries that have received regulatory approval. The following table summarizes the adverse event rate for the Allurion Gastric Balloon System in use outside of the United States (Table 11).

Table 11: Top Ten Adverse Events (December 2015 – December 2025)*

Adverse Event	Total Count	Adverse Event % Dec 2015 - Dec 2025**
Intolerance	332	0.163%
Gastric Outlet Obstruction	229	0.112%
Hyperinflation	194	0.095%
Small Bowel Obstruction	111	0.054%
Gastric Perforation	40	0.020%
Pancreatitis	38	0.019%
GI Bleed	28	0.014%
Delayed Intestinal Transit	23	0.011%
Dysphagia/Difficulty Swallowing	12	0.006%
Gastric Ulcer	9	0.004%

*Data from Allurion complaints system.

** Denominator is 204,031 for sales made during this period.

XIII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Gastroenterology-Urology Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIV. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The AGBS treatment was effective in promoting short-term limited weight loss at 48 weeks.

In both the mITT and ITT populations, using the imputation methods pre-specified in the Statistical Analysis Plan, Co-Primary Effectiveness Endpoint #1 was met, with 58.0% and 59.2% of AGBS subjects, respectively, having achieved at least 5% TBWL at 48 weeks. Of note, at 24 weeks in the mITT population, 58.5% of AGBS subjects were responders, and at 40 weeks, 63.9% of AGBS subjects were responders. In addition, 32.1% of subjects in the AGBS group had greater than or equal to 10% TBWL at 48 weeks.

In the mITT population using the MMRM method, the difference between the AGBS and control groups at 48 weeks was 3.05% (95% CI: 2.09, 4.00). Also, using the LOCF method, the difference between the two groups at 48 weeks was 3.77% (95% CI: 2.69, 4.86). For Co-Primary Effectiveness Endpoint #2, neither of these met the super superiority margin of 3.0%. However, the difference in weight loss was clinically meaningful for the AGBS group.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory as well as data collected in a clinical study conducted to support PMA approval as described above.

The adverse events observed in the AUDACITY trial were typical of those associated with intragastric balloons, including nausea, abdominal pain, and vomiting. There were no subject deaths and no small bowel obstructions in the trial. The types, rates, and severity of non-serious adverse events, including device-related adverse events, are similar to other commercially available intragastric balloons.

A total of 8 (3.0%) subjects experienced device-related SAEs and there were no procedure-related SAEs. With the exception of one subject who had an underlying condition that led to an SAE, all other SAEs resolved without sequelae.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The percentage of the AGBS subjects who achieved ≥ 5% TBWL was 58.0% at 48 weeks. Therefore, co-primary endpoint #1 of the clinical study was met. Weight loss at 48 weeks was 6.87 % and 3.09 % in the AGBS and control groups, respectively, with a difference of 3.77% (95% CI 2.69, 4.86). Though super superiority margin was not met for co-primary

endpoint #2, the weight loss achieved by the treatment group was clinically meaningful when treatment included 2 balloons placed during a 10-month period.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. In the clinical study, a total of 8 (3.0%) subjects experienced device-related SAEs and there were no procedure-related SAEs. Of the 18 SAEs reported in the AGBS treatment group, 15 were device-related and occurred in 8 subjects after placement of Allurion Balloon #2 There was one subject that experienced gastric perforation and peritonitis.

Additional factors to be considered in determining probable risks and benefits for the Allurion Gastric Balloon System device included: The safety outcomes demonstrates that risks inherent in the indwelling of a fluid filled intragastric balloon (IGB) are present in this IGB. There are inherent, device class-related risks associated with the IGB. However, there are increased benefits of this intragastric balloon with new technology because it obviates the need for anesthesia and endoscopy, which is required for other approved intragastric balloons.

1. Patient Perspective
   This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data support that for short-term limited weight loss in adult individuals with obesity between the ages of 22 years and 65 years with a body mass index (BMI) $\geq$ 30 kg/m^2 and $\leq$ 40 kg/m^2 in conjunction with a moderate intensity lifestyle modification therapy program the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the Allurion Gastric Balloon System when used in accordance with the indications for use. Subjects treated with the Allurion Gastric Balloon System had a weight loss of 6.86% at 48 weeks compared to 3.09% weight loss in control subjects. About 58% of subjects treated with the Allurion Balloon System lost at least 5% of their baseline weight. The safety profile for the Allurion Gastric Balloon System is reasonable, with eight subjects experiencing eighteen device- or procedure-related SAEs among 185 subjects in whom received the Allurion Gastric Balloon in the US pivotal study. Most AEs were mild or moderate and were reversible with device removal. In conclusion, the Allurion Gastric Balloon system is safe and effective for short-term limited weight loss in adult patients with BMI $\geq$ 30 kg/m^2 and $\leq$ 40 kg/m^2 when treatment included 2 balloons placed during a 10-month period and used in conjunction with a supervised weight management program.

XV. CDRH DECISION

CDRH issued an approval order on March 20, 2026. The final clinical conditions of approval cited in the approval order are described below.

PMA Post-Approval Study - The Allurion Gastric Balloon System: Post Approval Study is a multicenter, open-label study for the continuing evaluation and periodic reporting of the safety and effectiveness of the Allurion Gastric Balloon System for short term limited weight loss in adults with obesity 22 to 65 years of age with a BMI of ≥ 30 kg/m^2 and ≤ 40 kg/m^2 who have failed to achieve and maintain weight-loss with a supervised weight control program. Subjects will be treated with the Allurion Gastric Balloon System in conjunction with a diet and exercise plan. Subjects will be treated with the Allurion Gastric Balloon for 10 months. The study will be conducted at up to 15 US centers. A maximum of 250 patients will be treated to achieve 200 patients with evaluable data at 48 weeks. The enrollment at each site will have a maximum of 30 subjects. Patients will have balloons placed on the initial treatment day and approximately at the week 32 visit. Prior to the placement of the second Balloon, the first Balloon must be confirmed via imaging to have exited the body. If a patient declines to receive the second Balloon, they will be exited from the study.

The primary study endpoint is to demonstrate that the rate of device or procedure related serious adverse events (SAEs) (Clavien-Dindo Class III or greater) does not exceed 9% at 48 weeks. The secondary endpoint is to evaluate device effectiveness after the sequential balloon therapy. The effectiveness endpoints are evaluated as:

1) the percentage of patients with at least 5% %TBWL (responder rate) and
2) the mean %TBWL at 48 weeks.

The secondary safety endpoint is evaluating the percentage of patients, frequency and severity of individual Adverse Events that are device or procedure related (e.g. abdominal pain, nausea, vomiting, bloating) during the balloon therapy period.

The observational effectiveness endpoints are:

1) Percentage of patients with at least 6%, 7%, 8%, 9%, and 10% TBWL at Weeks 16, 24, 32, and 48
2) Summary Statistics for greatest %TBWL, and week at which greatest %TBWL occurred
3) Percentage of patients who maintained at least 40%, 50%, 60%, 70%, 80%, 90% and $\geq$ 90% of their %TBWL at Week 48

From the date of study protocol approval, you must meet the following timelines for:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

You must submit separate periodic PAS reports on the progress and data of the Allurion Post Approval Study as follows:

- PAS Progress Reports every six months until subject enrollment has been completed, and annually thereafter.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every 3 months in addition to your periodic (6months) PAS Progress Reports, until FDA notifies you otherwise.
- Submit the Final PAS Report three (3) months from study completion (i.e. last subject's last follow-up date).

The applicant's manufacturing facility was inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820), which was in effect at the time of the inspection. As of February 2, 2026, the revised part 820, referred to as the Quality Management System Regulation (QMSR), is effective.

XVI. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.