SUMMARY OF SAFETY AND PROBABLE BENEFIT (SSPB)

I. GENERAL INFORMATION

Device Generic Name: Dural Arteriovenous Fistula Liquid Embolic

Device Trade Name: Precipitating Hydrophobic Injectable Liquid (PHIL) Liquid Embolic System

Device Procode: SGF

Applicant's Name and Address: MicroVention, Inc.
35 Enterprise
Aliso Viejo, CA 92656

Date(s) of Panel Recommendation: None

Humanitarian Device Exemption (HDE) Number: H240004

Humanitarian Use Device (HUD) Designation Number: HUD # 16-0363

Date of HUD Designation: June 7, 2016

Date of Notice of Approval to Applicant: December 31, 2025

II. INDICATIONS FOR USE

The PHIL Liquid Embolic System is indicated for use in the treatment of intracranial dural arteriovenous fistulas (dAVFs).

The indication for use statement has been modified from that granted for the HUD designation. The HUD designation was for the "treatment of intracranial and spinal dural arteriovenous fistulas (dAVFs)." It was modified for the HDE approval because performance data was only provided to support the safety and probable benefit of using the PHIL Liquid Embolic System for the treatment of intracranial dAVFs and not for spinal dAVFs.

III. CONTRAINDICATIONS

The use of the PHIL device is contraindicated when any of the following conditions exist:

- Patient has a severe iodine allergy.
- Optimal microcatheter placement is not possible.
- Provocative testing indicates intolerance to the occlusion procedure.
- Patient has vasospasm that stops blood flow.

- Patients with known hypersensitivity to nickel as the device packaged in glass syringes may contain nickel.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the PHIL Liquid Embolic System labeling.

V. DEVICE DESCRIPTION

The PHIL Liquid Embolic System (**Figure 1**) is a non-adhesive liquid embolic agent made of a co-polymer dissolved in DMSO (dimethyl sulfoxide). An iodine component is chemically bonded to the co-polymer for radiopacity during injection. PHIL is a permanently implanted device with direct intravascular tissue and blood contact (> 30 days). The PHIL Liquid Embolic System consists of the following components:

- A sterile, non-pyrogenic pre-filled 1.0 mL syringe of DMSO. DMSO is the flushing solution.
- A sterile, non-pyrogenic pre-filled 1.0 mL syringe of the PHIL liquid embolic. PHIL is a liquid co-polymer with iodine for radiopacity.
- Universal microcatheter adapter is packaged with the device for use during embolic delivery.

Figure 1. PHIL Liquid Embolic System with syringe and universal microcatheter adapter.

The PHIL liquid embolic is delivered by slow, controlled injection through a microcatheter into the vessel or malformation under fluoroscopic control. The DMSO solvent dissipates into the blood, causing the co-polymer to precipitate in situ into a coherent embolus. The PHIL liquid embolic immediately forms a barrier as the polymeric embolus solidifies from the outside to the inside, while traveling more distally in the lesion. The final solidification of the product occurs within three minutes for any viscosity.

The PHIL Liquid Embolic System is available in the following concentrations: PHIL 25%, PHIL 30%, and PHIL 35%. While chemically identical, the different concentrations reflect the weight percentage of the polymer contained in solution. Consequently, the higher the weight percentage, the higher the viscosity. PHIL 25% represents a lower viscosity compared to PHIL 30% or 35%, which are of higher viscosity.

PHIL 25% is recommended when distal access close to the fistula cannot be achieved. PHIL 25% is less viscous and can travel more distally and penetrate deeper into the fistula due to its lower viscosity. PHIL 30% is recommended when access is distal and at the level of the fistula. PHIL 35% is recommended for embolizing higher flow and larger fistulous components. The appropriate PHIL formulation should be chosen by the physician based on their medical judgement and preference and the patients' specific vessel anatomical characteristics. A DMSO compatible delivery microcatheter (Headway DUO, Headway 17/21 or Scepter C/XC/Mini Occlusion Balloon Microcatheters) intended for use in the neurovascular system is used to access the embolization target site.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Conventional procedures used in the treatment of intracranial dAVFs include endovascular embolization and/or surgery, including stereotactic radiosurgery and dAVF surgery. The decision on treatment course is based on an analysis of an individual's symptoms as well as an analysis of the venous drainage. Treatment strategy is decided by a multidisciplinary neurovascular team and must consider the individual risk of each dAVF. In most cases, embolization is proposed as the first treatment option to try to obtain a complete and definitive cure of the dAVF. Surgery may be required in some locations or in the case of embolization failure. A subset of high-risk lesions requires surgical intervention, with certain anatomic locations of dAVFs being more amenable to surgery.

In the United States (U.S.), there is no comparable device (liquid embolic agent) available with the indication of treatment of intracranial dAVFs.

VII. MARKETING HISTORY

The PHIL Liquid Embolic System has been CE (Conformité Européenne) marked since 2014.

Currently, the list of approved countries includes: Albania, Argentina, Armenia, Australia, Azerbaijan, Bangladesh, Belarus, Bolivia, Bosnia and Herzegovina, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, European Union, Georgia, Guatemala, Hong Kong, Indonesia, Iran, Israel, Kazakhstan, Korea (Republic of), Lebanon, Malaysia, Mexico, Mongolia, Morocco, New Zealand, Pakistan, Panama, Paraguay, Peru, Russia Federation, Saudi Arabia, Serbia, Singapore, South Africa, Taiwan, Tajikistan, Thailand, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Ukraine, United Arab Emirates, Uruguay, Uzbekistan, Vietnam.

The PHIL Liquid Embolic System has not been withdrawn from marketing for any reason relating to the safety and probable benefit of the device.

VIII. PROBABLE ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

Potential complications include, but are not limited to:

- Hematoma at the puncture site and other access site complications such as fistula, pseudo-aneurysm, pain, tenderness, inflammation, necrosis and granuloma.
- Non-target arterial thrombosis.
- Ischemic events due to embolic migration, vasospasm, thrombosis.
- Hemorrhagic accidents: vascular rupture, perforation.
- Hemodynamic changes induced by the embolization may result in hemorrhagic complications.
- Ischemic or hemorrhagic complications may result in various functional neurological deficits, transient ischemic attack (TIA), stroke, or death.
- Allergic reactions or sub-acute inflammatory response.
- Device- or procedure-related complications such as arrhythmia, contrast related complications (e.g., burning sensation, nausea, contrast nephropathy), headache, infection, nerve damage or cranial nerve palsy, pulmonary embolism, seizures, thrombocytopenia, visual complications.
- This device uses fluoroscopy, which presents potential risks associated with X-ray exposure. The risks of angiographic and fluoroscopic X-ray radiation doses to the patient include risks such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and the number of procedures increase.

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

Objectives. The objectives of the laboratory studies were to ensure the device is biocompatible, to validate the sterilization of the device, to evaluate that the device meets design specifications and applicable standards, and to demonstrate that the device has continued performance to support a shelf-life of two (2) years, with its current packaging. Tests were evaluated to assess the performance of both the PHIL liquid embolic, including the syringe, and the universal microcatheter adapter.

Biocompatibility

Biocompatibility testing for all materials used to manufacture the PHIL Liquid Embolic System were performed in accordance with ISO 10993-1, "*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*." Table 1 and Table 2 outline the biocompatibility tests conducted for the PHIL liquid embolic and the universal microcatheter adapter, respectively.

Table 1. PHIL Liquid Embolic Biocompatibility Test Summary

Test	Results
ISO Minimum Essential Medium (MEM) Elution Test ISO 10993-5:2009	Non-cytotoxic to cells at the 24- and 48-hour readings: 0% cell lysis (Grade 0) at 24 and 48 hours.
ISO Agar Diffusion Test ISO 10993-5:2009	Non-cytotoxic to cells at 24- and 48-hour readings: 0% cell lysis (Grade 0) at 28 hours and slight cell lysis (Grade 1) at 48 hours.
ISO Guinea Pig Kligman Maximization Test ISO 10993-10:2021	No irritation (0% sensitized) at 24, 48, and 72 hours. The extracts were Grade I sensitization (weak). No weight loss, mortality, or evidence of toxicity.
Intracutaneous Injection Test in Rabbits ISO 10993-10:2021	No evidence of irritation at 24, 48, and 72 hours. Difference between test and control sites had a mean score of 0.0 for both mediums. Non-irritating.
ISO Systemic Injection in Mice ISO 10993-11:2017	No significant biological reaction was observed for any animals (test article) at 24, 48, and 72 hours as compared to negative control sites. No weight loss, mortality, or evidence of systemic toxicity.
Rabbit Pyrogen (Material-Mediated) Test ISO 10993-11:2017	All individual rabbits for both the test article and negative control showed a total rise of < 0.5 °C and were determined to be non-pyrogenic.
ISO In Vitro Ames Test – Salmonella Typhimurium and Escherichia Coli Reverse Mutation Genotoxicity Test ISO 10993-3:2014	A statistically significant increase in the number of revertant colonies was not observed with the test article as compared to negative controls. Non-mutagenic.
ISO In Vitro Chromosomal Aberration Effects Assay ISO 10993-3:2014	The test article extract prepared in Ham's F12 cell growth and 95% ethanol extraction mediums and evaluated in both the non-activated and activated systems for both the standard and confirmatory treatment periods were determined to be non-clastogenic (non-mutagenic).
ISO In Vitro Rodent Blood Micronucleus Assay ISO 10993-3:2014	All test article extracts prepared in normal saline and vegetable oil extraction mediums and evaluated in both male and female mice showed no statistically significant response and were considered non-clastogenic (non-mutagenic).
ISO Rabbit Intramuscular Implant with Histology Test in Rabbits – 2 Week Implant Duration	At 2 weeks, all animals gained weight. No signs of toxicity. Bioreactivity rating for the test article at 2 weeks was 4.4 (average of 3 animals), which indicates a slight reaction. However, due to the irregular surface

Test	Results
ISO 10993-6:2016	compared to the negative control, the test article was concluded to be non-reactive.
ISO Rabbit Intramuscular Implantation (13 Weeks) ISO 10993-6:2016	At 13 weeks, all animals gained weight. No signs of toxicity. Bioreactivity rating for the test article at 13 weeks was 3.1 (average of 3 animals), indicating a slight reaction as compared to negative control sites. Test site had some macrophages along with giant cells, but no giant cells at interface of control sites. Results were expected due to the nature of the test material and therefore test article was found to be non-reactive.
ISO Rabbit Intramuscular Implantation (26 Weeks) ISO 10993-6:2016	At 26 weeks, all animals gained weight. No signs of toxicity. Bioreactivity rating for the test article at 26 weeks was 0.0 (average of 3 animals), indicating no reaction as compared to negative control sites. Test article is non-reactive.
ASTM Hemolysis Test –Rabbit Blood –Direct/Indirect ISO 10993-4:2017	Direct contact: Solid test article was slightly hemolytic (3.43% hemolysis) compared to baseline. Indirect contact: Extract test article was non-hemolytic (0.0% hemolysis) as compared to baseline.
ISO Unactivated Partial Thromboplastin Time (UPTT) – Direct ISO 10993-4:2017	Test article: UPTT is 175.6 seconds. Negative control: UPTT is 235.7 seconds. Untreated control: UPTT is 239.3 seconds. Positive control: UPTT is 102.1 seconds. Test article is a mild activator (50-74%), which meets the guideline of > 50%.
ISO Complement Activation Test – Direct ISO 10993-4:2017	Exhibited no statistically significant increase in C3b or SC5b-9 when compared to untreated and negative control plasma at 90 minutes. C3 and C5 complement proteins non-activated by test article compared to negative control.

Table 2. PHIL Universal Adapter Biocompatibility Test Summary

Test	Results
ISO MEM Elution Test – 1x Complete MEM (CMEM) Cell Growth Medium Extract ISO 10993-5:2009	No cytotoxicity or cell lysis was noted in any of the test wells (Grade 0). No pH shift was observed at 48 hours. The reagent control, negative control, and the positive control performed as anticipated.
ISO Guinea Pig Kligman Maximization Test ISO 10993-10:2021	The test article extracts showed no evidence (Grade 0) of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test. No weight loss, mortality, or evidence of toxicity.
Intracutaneous Injection Test in Rabbits ISO 10993-10:2021	All animals appeared normal throughout the study. The overall mean difference was 0.0 and 0.2 for the sodium chloride (SC) and sesame oil (SO) extracts, respectively. The test article met the requirements of the test.
ISO Systemic Injection in Mice ISO 10993-11:2017	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.
Rabbit Pyrogen (Material-Mediated) Test ISO 10993-11:2017	No single animal showed a temperature rise of 0.5 °C or more above its baseline temperature. The total rise of the rabbits' temperature for 3 hours was 0.4 °C.
ASTM Hemolysis Test –Rabbit Blood – Indirect ISO 10993-4:2017	The test article is considered non-hemolytic with -0.7% hemolysis.
Exaggerated Extractables Testing ISO 10993-17:2023 ISO 10993-18:2020/A1:2022	By headspace – mass spectrometry (HS-MS) in water extracts: All margin of safety (MOS) values were ≥ 1 supporting acceptable toxicological risk. By gas chromatography – mass spectrometry (GC-MS) in all extracts: All MOS values were ≥ 1 supporting acceptable toxicological risk. By liquid chromatography – mass spectrometry (LC-MS) in all extracts: All MOS values were ≥ 1 supporting acceptable toxicological risk. By inductively coupled plasma – mass spectrometry (ICP-MS) in water extracts: All MOS values were ≥ 1 supporting acceptable toxicological risk.

Sterilization Validation

The PHIL Liquid Embolic System is sold sterile and for single use only. The PHIL device is provided as 3 components each packaged in a sealed sterile tray (liquid embolic syringe, DMSO syringe, and universal adapter). Each tray (containing the individual component) is batch sterilized and then assembled into a carton box. The PHIL Liquid Embolic System components are sterilized using steam sterilization in accordance with ISO 17665-1, "*Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*."

Sterilization testing was conducted on the PHIL empty syringe, PHIL liquid embolic syringes, and the universal adapter. Testing consisted of a sterility assurance level (SAL), pyrogen, and bioburden testing and all sterilization criteria were met.

In Vitro Performance Testing

The in vitro bench testing conducted on the PHIL Liquid Embolic System provides data on mechanical, chemical, and performance testing. All testing met acceptance criteria set forth by the design specifications and all applicable standards. Table 3 and Table 4 list the in vitro tests that were performed for the PHIL liquid embolic and universal microcatheter adapter, respectively.

Table 3. PHIL Liquid Embolic In Vitro Performance Testing

Test	Purpose/Objective	Acceptance Criteria	Results
Simulated Use	The liquid embolic must be injected at a rate easily controlled by the operator and delivered in a controlled manner. The liquid embolic must not excessively reflux.	Shall meet design specifications for filling a simulated use model.	Pass
Gel Permeation Chromatography (GPC) Analysis	Determine the stability of the PHIL liquid embolic polymer over its shelf-life.	The PHIL liquid embolic polymer molecular weight characteristics must remain stable over its shelf-life.	Pass
Precipitation Testing	The liquid embolic must solidify within a short time. The liquid embolic must be easily visualized.	Precipitated embolic shall meet design specifications for solidification and coloration.	Pass
Precipitate Dimensional Stability	The precipitated embolic must not expand or shrink over time.	Precipitated embolic shall meet design specifications for increase or decrease in size over time.	Pass

Test	Purpose/Objective	Acceptance Criteria	Results
Precipitate Weight Stability	The liquid embolic must not evaporate over time.	Evaporation after aging meets design specifications.	Pass
Precipitate Integrity	The liquid embolic must be cohesive and not break-off in circulation.	Compliant with standards for particulate matter generation for injections.	Pass
Radiation Stability	The liquid embolic precipitate must not degrade after exposure to imaging radiation.	The PHIL liquid embolic polymer molecular weight characteristics must remain stable after irradiation.	Pass
Microcatheter Compatibility	The liquid embolic must be compatible with microcatheters used with the device during the embolization procedure.	No observation of hub crack, catheter damage or deformity. Dynamic burst, air leakage, static burst, and force at break meet design specifications. No evidence of embolic-to-catheter adhesion or embolic fragmentation upon catheter extraction.	Pass
Refluxed Catheter Retraction	The catheter must not be difficult to remove in the case of unintended reflux.	The device must engender a force equivalent to or less than comparable products when the microcatheter is subjected to an equivalent reflux distance. No evidence of embolic-to-catheter adhesion or embolic fragmentation upon catheter extraction.	Pass
Coil Compatibility	The liquid embolic must be compatible with additional interventional devices.	The device must not chemically interact and exhibit deterioration or degradation when concomitantly used with interventional devices (coils).	Pass
Storage Temperature (Cold)	The liquid embolic must not degrade after exposure to extreme cold.	The PHIL liquid embolic polymer molecular weight characteristics and liquid viscosity must remain stable after exposure to extreme cold.	Pass

Test	Purpose/Objective	Acceptance Criteria	Results
Radiopacity	The liquid embolic must be visible under fluoroscopy during injection.	Must be visible under fluoroscopic imaging during injection.	Pass
Magnetic Resonance Imaging (MRI) Compatibility	The device must be magnetic resonance (MR) safe.	The liquid embolic must be MR safe per applicable ASTM standards.	Pass
Visual Inspection (Syringe)	The liquid embolic must be compatible with syringes used with the device.	No visual leakage past stopper or luer cap and no visual crazing or cracking of components with continuous DMSO exposure.	Pass
Torque Cap Removal	The cap must not be difficult to remove.	Luer removal torque meets design specifications.	Pass
Injection Force	The plunger must not require excessive force to inject.	Plunger injection force and variation meet design specifications. The injection pressure must not exceed the pressure capacity of the microcatheter system.	Pass

Table 4. Universal Adapter In Vitro Performance Testing

Test	Purpose/Objective	Acceptance Criteria	Results
Microcatheter Compatibility	The PHIL universal adapter must be compatible with all microcatheter hubs dedicated to liquid embolic injection.	The universal adapter must thread in properly to all compatible microcatheters.	Pass
Total Length	The PHIL universal adapter length must not exceed dimension specifications.	The universal adapter must not exceed dimension specifications.	Pass
Intuitive Use	The PHIL universal adapter must be easily manipulated and connected between the syringe of the liquid embolic and the hub of the microcatheter.	Physicians will rate the universal adapter as intuitive.	Pass
Dead Space	The PHIL universal adapter must decrease the dead space of the microcatheter used for the liquid embolic injection.	The universal adapter must not create dead space that is greater than the hubs of compatible microcatheters.	Pass

Test	Purpose/Objective	Acceptance Criteria	Results
Reflux	The PHIL universal adapter must not move when correctly positioned to avoid any reflux of liquid embolic in the hub even with increased injection pressure.	There should be no liquid embolic reflux back into the hub when the universal adapter is properly engaged and seated inside the microcatheter hub and pressurized.	Pass
Female Luer Lock	The PHIL universal adapter female luer lock must be compatible with standard male luer locks.	The female luer lock must properly engage with the male luer lock.	Pass
Leakage	When the PHIL universal adapter is correctly connected, it must not leak at the level of the syringe and/or at the level of the hub connection.	There is no leakage between the male and female luer locks when properly engaged and pressurized.	Pass
Injection Durability	The PHIL universal adapter must be durable enough to support long injections/ procedure times.	The universal adapter must not leak after performing multiple injections.	Pass
Female Luer Lock Durability	The PHIL universal adapter female luer lock must support multiple syringe connections.	The universal adapter threads must not deform and/or crack after multiple uses.	Pass
Component Cohesiveness	The PHIL universal adapter components must not separate unintentionally during manipulation.	The universal adapter components must stay together.	Pass
DMSO Compatibility/ Integrity, Universal Adapter	The PHIL universal adapter must maintain integrity after DMSO exposure.	No surface damage, cracking, crazing after exposure to DMSO.	Pass
DMSO Compatibility/ Leakage, Universal Adapter	The PHIL universal adapter must not leak after DMSO exposure.	No liquid leakage of the adapter or adapter/microcatheter junction when pressurized after exposure to DMSO.	Pass
DMSO Compatibility/ Leachability, Universal Adapter	The PHIL universal adapter must not leak toxic material to humans after DMSO exposure.	The toxicity of leachable materials shall pose no significant risk to humans after exposure to DMSO.	Pass
Embolic Compatibility/ Integrity, Universal Adapter	The PHIL universal adapter must maintain integrity after liquid embolic exposure.	No surface damage, cracking, crazing after exposure to PHIL liquid embolic.	Pass

Test	Purpose/Objective	Acceptance Criteria	Results
Embolic Compatibility/ Leakage, Universal Adapter	The PHIL universal adapter must not leak after liquid embolic exposure.	No liquid leakage of the adapter or adapter/microcatheter junction when pressurized after exposure to PHIL liquid embolic.	Pass
Embolic Compatibility/ Leachability, Universal Adapter	The PHIL universal adapter must not leak toxic material to humans after liquid embolic exposure.	The toxicity of leachable materials shall pose no significant risk to humans after exposure to PHIL liquid embolic.	Pass
Injection Force with Universal Adapter	The injection force of the syringe connected to the universal adapter must not be excessive.	Plunger injection force meets design specifications.	Pass

Shelf-Life and Packaging Validation

The shelf-life stability for the PHIL Liquid Embolic System with its current packaging has been tested and demonstrated to meet performance test criteria for up to two years. The PHIL Liquid Embolic System will be labeled for a two-year shelf-life. Packaging validations were conducted on the PHIL Liquid Embolic System to confirm suitability for transportation and storage conditions. The PHIL Liquid Embolic System packaging configuration consists of individual pre-filled syringes (pre-filled liquid embolic, pre-filled DMSO) and universal adapters placed into a polycarbonate tray sealed with a Tyvek lid and placed into a shelf carton. The samples were pre-conditioned for simulated shipping and sterilized. The dimensional and functional attributes of the packaged devices were tested and met acceptance criteria. In addition, packaging integrity testing (pouch and carton) was verified and met acceptance criteria to support the 2-year shelf-life.

B. Animal Studies

Objectives. The objective of the animal study was to evaluate the safety and performance of the PHIL Liquid Embolic System as an embolization device in a porcine rete model at acute (0 days) and chronic (14-, 90- and 180-days) time points in comparison to a control liquid embolic.

Results. The performance and handling scores of the PHIL embolization procedure were similar to those of the control liquid embolic. All animals in the study (n=28) survived to their scheduled termination time points. At necropsy, none of the harvested organs displayed gross abnormalities in any of the animals. On histopathology, all embolized vessels except one were completely occluded with the PHIL liquid embolic material alone or combined with blood clot components (n=24 rete). All embolized vessels in the control group animals were completely occluded (n=4 rete).

Histopathology showed a mild inflammatory response to the embolized material in both test and control chronic groups. Vessel wall perforation was rare, with a single instance of embolic material extravasation in each of the test and control groups. Perivascular tissue surrounding PHIL embolized vessels appeared generally normal with no remarkable fibrosis or extravascular hemorrhage. There was no evidence of off-target vascular occlusion or migration of the PHIL liquid embolic material to unintended locations.

Conclusions. The results of the animal study show that the PHIL Liquid Embolic System met performance and safety expectations at acute and chronic time points compared to a control liquid embolic.

X. SUMMARY OF CLINICAL INFORMATION

The applicant performed a clinical study in the U.S. to establish a reasonable assurance of safety and probable benefit of the PHIL Liquid Embolic System in the treatment of intracranial dAVFs under investigational device exemption (IDE) G170203 (entitled "PHIL dAVF: Study of PHIL Embolic System in the Treatment of Intracranial Dural Arteriovenous Fistulas (dAVF)"). A summary of the clinical study is presented below.

Study Overview

The "PHIL dAVF" study was a prospective, multi-center, single-arm clinical study conducted at 13 centers in the U.S., with 12 centers that enrolled patients, to evaluate the safety and probable benefit of the PHIL Liquid Embolic System in treating intracranial dAVFs. The study enrolled 88 subjects between September 2018 and November 2021 of which 64 subjects were treated with the PHIL device. Twenty-four subjects were consented but not enrolled into the study, including 19 screen failures and five subjects who withdrew prior to the treatment. All patients were scheduled to return for follow-up examinations at 30 days (±14 days), 3 months (-2/+4 weeks), and 6 months (-3/+6 weeks). Sixty-three (63) of the enrolled patients completed the 30-day and 3-month visits and sixty-two (62) of the patients completed a 6-month visit. The primary analysis for safety and probable benefit used the Full Analysis Set (FAS) population defined as all enrolled patients in whom the PHIL device was implanted and had available primary endpoint data at 6 months (N=62).

The study used a Data Safety and Outcomes Monitoring Committee (DSOMC) to monitor the study safety and adjudicate all adverse events (AEs) that occurred in the study. The study also used an independent core lab which adjudicated angiographic outcomes including target vessel occlusion.

Clinical Inclusion and Exclusion Criteria

Enrollment in the "PHIL dAVF" study was limited to patients who met ALL of the following inclusion criteria:

- Patient was ≥ 22 and ≤ 80 years of age.

- Patient was willing and capable of complying with all study protocol requirements, including the specified follow-up period.
- Patient or authorized legal representative signed and dated an Institutional Review Board (IRB)-approved written informed consent prior to initiation of any study procedures.
- Patient had an intracranial dAVF that could be treated by embolization with PHIL without the need for other liquid embolization products (e.g., Onyx, n-BCA (n-butylcyanoacrylate)).
- Patient had an intracranial dAVF that was deemed appropriate for embolization with PHIL without significantly increased risk to collateral or adjacent territories.

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

- Patient had modified Rankin Scale (mRS) of > 3 or another neurological deficit not due to stroke that might confound the neurological assessments.
- Patient had multiple dAVFs to be treated.
- Patient had dAVF that required pre-planned treatment with adjunctive treatments (i.e., embolic coils, surgical resection, etc.).
- Patient presented with an intracranial mass or was currently undergoing radiation therapy for carcinoma or sarcoma of the head or neck region.
- Patient had known allergies to DMSO, iodine, or heparin.
- Patient had a history of life-threatening allergy to contrast media (unless treatment for allergy was tolerated).
- Patient was experiencing (or had experienced) an evolving, acute, or recent disabling ischemic stroke, had conditions placing them at high risk for ischemic stroke, or had exhibited ischemic symptoms, such as transient ischemic attacks, minor strokes, or stroke-in-evolution within the prior 3-month timeframe.
- Patient had an acute myocardial infarction within 30 days prior to index procedure.
- Patient had or planned to have a major surgical procedure (i.e., intra-abdominal or intrathoracic surgery or any surgery/interventional procedure involving cardiac or vascular system) within 30 days of the index procedure.
- Patient was participating in another clinical study which may interfere with the outcome measurements for this study.
- Female patient was pregnant.
- Patient had an acute or chronic life-threatening illness other than the neurological disease treated in this study, including but not limited to any malignancy or debilitating autoimmune disease.
- Patient had existing severe or advanced co-morbid conditions which significantly increased general anesthesia and/or surgical risk, including but not limited to advanced chronic obstructive pulmonary disease (COPD), uncontrolled hypertension/diabetes, congestive heart failure, chronic or acute kidney disease.
- Patient had evidence of active infection at the time of treatment.
- Patient had dementia or cognitive or psychiatric problem that prevented the patient from completing required follow-up.
- Patient had co-morbid conditions that might limit survival to < 24 months.

- Patient had a history of bleeding diathesis or coagulopathy, international normalized ratio (INR) greater than 1.5, or refused blood transfusions.

Angiographic Exclusion Criteria

- Patient had severe calcification or vascular tortuosity that may preclude the safe introduction of the sheath, guiding catheter, or access to the lesion with the microcatheter.
- Patient had a contra-indication to digital subtraction angiography/angiogram (DSA), computed tomography (CT) scan, or MRI/ magnetic resonance angiography/angiogram (MRA).
- Patient had a history of intracranial vasospasm not responsive to medical therapy.
- Patient had extra-cranial stenosis or parent vessel stenosis > 50% proximal to the target lesion to be treated.

Safety Outcomes

The pre-specified primary safety outcome in the "PHIL dAVF" study was defined as the proportion of subjects with neurological death or ipsilateral stroke within the first 30 days following completion of the first PHIL treatment procedure. Neurologic death was defined as subject death reported as having resulted from a neurologic cause. Stroke was defined as a new focal neurological deficit in a defined vascular distribution of abrupt onset with symptoms persisting for > 24 hours and a neuro-imaging study or other quantitative study that did not indicate a different etiology. This included ischemic and hemorrhagic strokes.

Probable Benefit Outcome

The pre-specified primary probable benefit outcome of the "PHIL dAVF" study was defined as angiographic occlusion of the pre-specified target vessel intended for treatment at procedure following completion of the first PHIL treatment procedure. Angiographic occlusion of the pre-specified target vessel was defined as complete cessation of flow at the point of embolic agent administration at the target vessel.

Patient Demographics

Baseline demographics for the sixty-two (62) subjects in the FAS population are summarized in Table 5. Baseline characteristics pertaining to the patients' dAVFs are summarized in Table 6. The concentration of PHIL used among study subjects is also shown in Table 6. The majority of cases used either PHIL 25%, PHIL 30% or a combination of PHIL concentrations.

Table 5. Baseline Demographics

Subject Characteristic	**N=62**
Age (Years)	
Mean ± SD (Standard Deviation)	56.6 ± 13.31
Range (Min, Max)	31, 78
Sex	
Female	19 (30.6%)
Male	43 (69.4%)
Race	
Asian	4 (6.5%)
Black or African American	6 (9.7%)
Native Hawaiian or Other Pacific Islander	0 (0.0%
White	45 (72.6%)
Not Willing to Provide	2 (3.2%)
Unknown	3 (4.8%)
Other	2 (3.2%)
Ethnicity	
Hispanic or Latino	6 (9.7%)
Not Hispanic or Latino	53 (85.5%)
Unknown	3 (4.8%)

Table 6. Baseline Characteristics of Target dAVFs and Procedural Characteristics

dAVF Characteristic	**N=62, n (%)**
Borden classification	
Type I	23 (37.1%)
Type II	11 (17.7%)
Type III	28 (45.2%)
dAVF location*	
Cavernous sinus and para-cavernous	2/62 (3.2%)
Foramen magnum	1 (1.6%)
Sigmoid sinus	16 (25.8%)
Superior sagittal sinus	13 (21.0%)
Superior petrosal sinus	1 (1.6%)
Tentorial	3 (4.8%)
Transverse sinus	25 (40.3%)
Vein of Galen, straight sinus	1 (1.6%)
Other	12 (19.4%)
dAVF rupture status	
Ruptured	7 (11.3%)
Unruptured	55 (88.7%)
Days between rupture and treatment	
≤ 30 days	4 (6.5%)

dAVF Characteristic	N=62, n (%)
> 30 days	3 (4.8%)
Previous treatment	
Previously treated dAVF	9 (14.5%)
Previously untreated dAVF	53 (85.5%)
PHIL concentration used in study procedure	
PHIL 25%	26 (41.9%)
PHIL 30%	18 (29.0%)
PHIL 35%	4 (6.5%)
More than one concentration used	14 (22.5%)

*A fistula can be reported with multiple locations.

Probable Benefit Results

The pre-specified primary probable benefit outcome of the "PHIL dAVF" study was defined as angiographic occlusion of the pre-specified target vessel intended for treatment at procedure following completion of the first PHIL treatment procedure. Angiographic occlusion of the pre-specified target vessel was defined as complete cessation of flow at the point of embolic agent administration at the target vessel. The primary probable benefit outcome was evaluated descriptively. In the FAS population, the primary probable benefit outcome success rate was 96.77% [60/62, lower confidence limit (LCL) 86.28% – upper confidence limit (UCL) 99.81%] for the worst-case analysis and 98.39% (61/62, LCL 88.98%–UCL 99.99%) for the best-case analysis as adjudicated by the core lab (Table 7). Best- and worst-case analyses were conducted by considering illegible angiographic imaging as a success and failure, respectively. The complete occlusion (100%) of the dAVF was not evaluated post-operative; therefore, the long-term stability of the PHIL embolization procedure is unknown nor whether patients require further retreatment.

Table 7. Primary Probable Benefit Outcome

Probable Benefit	n/N (%)	98.75% Confidence Interval (CI) (LCL, UCL)
Worst-case analysis[1]	60/62 (96.77%)	(86.28, 99.81)
Best-case analysis[2]	61/62 (98.39%)	(88.98, 99.99)

[1] Worst-case analysis: Illegible angiographic imaging was considered as a failure for probable benefit assessment.
[2] Best-case analysis: Illegible angiographic imaging is considered as a success for probable benefit assessment.

Safety Results

The pre-specified primary safety outcome in the "PHIL dAVF" study was defined as the proportion of subjects with neurological death or ipsilateral stroke within the first 30 days following completion of the first PHIL treatment procedure. The primary safety outcome

was evaluated descriptively. None of the subjects in the FAS population experienced a neurological death or ipsilateral stroke within the first 30 days following completion of the first PHIL treatment procedure as adjudicated by the DSOMC, yielding a primary safety outcome event rate of 0% (Table 8). No primary safety outcome events were observed through the 6-month follow-up period.

Table 8. Primary Safety Outcome

Primary Safety Outcome	**n/N (%)**	**98.75% Exact CI (LCL, UCL)**
Neurological death within 30 days following **first** PHIL treatment	0/62 (0.00%)	(0.00, 7.86)
Ipsilateral stroke within 30 days following **first** PHIL treatment	0/62 (0.00%)	(0.00, 7.86)

The DSOMC reviewed all AEs and adjudicated AEs for relatedness to the device or procedure as shown in Table 9 and Table 10, respectively. One AE (failure to thrive) was reported by the site as a serious adverse event (SAE), which the DSOMC adjudicated as procedure-related.

Table 9. Device-related Adverse Events

System Organ Class **Preferred Term**	**n/N (%) [# Events]**
Nervous system disorders	1/62 (1.6%) [1]
Facial paralysis	1/62 (1.6%) [1]

Table 10. Procedure-related Adverse Events

System Organ Class **Preferred Term**	**N=62** **# Subjects (%) [# Events]**
Eye disorders	2 (3.2%) [2]
Visual impairment	1 (1.6%) [1]
Visual acuity reduced	1 (1.6%) [1]
Injury, poisoning and procedural complications	10 (16.1%) [11]
Radiation alopecia	4 (6.5%) [4]
Procedural nausea	2 (3.2%) [2]
Vascular access site hematoma	1 (1.6%) [1]
Procedural headache	1 (1.6%) [1]
Urinary tract procedural complication	1 (1.6%) [1]
Vascular access site pain	1 (1.6%) [1]
Vascular access site pseudoaneurysm	1 (1.6%) [1]
Metabolism and nutrition disorders	1 (1.6%) [1]
Failure to thrive	1 (1.6%) [1]

System Organ Class Preferred Term	N=62 # Subjects (%) [# Events]
Musculoskeletal and connective tissue disorders	1 (1.6%) [1]
Neck pain	1 (1.6%) [1]
Nervous system disorders	5 (8.1%) [6]
Procedural headache	3 (4.8%) [3]
Headache	1 (1.6%) [1]
Paresthesia	1 (1.6%) [1]
Cerebral vasoconstriction	1 (1.6%) [1]
Respiratory, thoracic and mediastinal disorders	1 (1.6%) [1]
Dyspnea	1 (1.6%) [1]

A summary of the overall adverse events organized by System Organ Class and Preferred Term of the Medical Dictionary for Regulatory Activities (MedDRA) is shown in Table 11.

Table 11. All Adverse Events by MedDRA System Organ Class and Preferred Term

System Organ Class Preferred Term	N=62 #Subjects (%) [# Events]
Cardiac disorders	1 (1.6%) [1]
Acute myocardial infarction	1 (1.6%) [1]
Ear and labyrinth disorders	3 (4.8%) [4]
Tinnitus	2 (3.2%) [2]
Ear pain	1 (1.6%) [1]
Dysacusis	1 (1.6%) [1]
Eye disorders	4 (6.5%) [4]
Cataract	1 (1.6%) [1]
Visual acuity reduced	1 (1.6%) [1]
Diplopia	1 (1.6%) [1]
Visual impairment	1 (1.6%) [1]
General disorders and administration site conditions	2 (3.2%) [2]
Malaise	1 (1.6%) [1]
Swelling face	1 (1.6%) [1]
Infections and infestations	6 (9.7%) [7]
COVID-19	4 (6.5%) [4]
Pneumonia	1 (1.6%) [1]
Ear infection	1 (1.6%) [1]
Upper respiratory tract infection	1 (1.6%) [1]

System Organ Class Preferred Term	N=62 #Subjects (%) [# Events]
Injury, poisoning and procedural complications	14 (22.6%) [16]
Radiation alopecia	4 (6.5%) [4]
Procedural nausea	2 (3.2%) [2]
Vascular access site pseudoaneurysm	1 (1.6%) [1]
Urinary retention postoperative	1 (1.6%) [1]
Skin laceration	1 (1.6%) [1]
Vascular access site hematoma	1 (1.6%) [1]
Head injury	1 (1.6%) [1]
Thermal burn	1 (1.6%) [1]
Urinary tract procedural complication	1 (1.6%) [1]
Vascular access site pain	1 (1.6%) [2]
Procedural headache	1 (1.6%) [1]
Metabolism and nutrition disorders	1 (1.6%) [1]
Failure to thrive	1 (1.6%) [1]
Musculoskeletal and connective tissue disorders	4 (6.5%) [5]
Arthralgia	2 (3.2%) [2]
Muscle spasms	1 (1.6%) [1]
Arthritis	1 (1.6%) [1]
Neck pain	1 (1.6%) [1]
Nervous system disorders	20 (32.3%) [22]
Headache	7 (11.3%) [7]
Procedural headache	3 (4.8%) [3]
Seizure	2 (3.2%) [2]
Facial paralysis	1 (1.6%) [1]
Ischemic stroke	1 (1.6%) [1]
Cerebral vasoconstriction	1 (1.6%) [1]
Paresthesia	1 (1.6%) [1]
Transient ischemic attack	1 (1.6%) [1]
Dizziness	1 (1.6%) [1]
Facial paresis	1 (1.6%) [1]
Hemiparesis	1 (1.6%) [1]
Papilloedema	1 (1.6%) [1]
Syncope	1 (1.6%) [1]
Psychiatric disorders	1 (1.6%) [1]
Hallucination	1 (1.6%) [1]
Renal and urinary disorders	1 (1.6%) [1]
Acute kidney injury	1 (1.6%) [1]

System Organ Class Preferred Term	N=62 #Subjects (%) [# Events]
Respiratory, thoracic and mediastinal disorders	1 (1.6%) [1]
Dyspnoea	1 (1.6%) [1]
Skin and subcutaneous tissue disorders	1 (1.6%) [1]
Chronic spontaneous urticaria	1 (1.6%) [1]
Vascular disorders	2 (3.2%) [2]
Aortic dissection	1 (1.6%) [1]
Hypertension	1 (1.6%) [1]

Secondary Outcomes

Secondary outcome measures of the "PHIL dAVF" study in the FAS population is summarized in Table 12. As shown in Table 12, no events were observed for new onset or worsening permanent morbidity, intracranial hemorrhage, or device-related mortality. One out of sixty-two subjects (1.6%) experienced a new onset of cranial nerve palsy at 6 months and one patient (1/62, 1.6%) experienced a device-related AE causing facial paralysis which did not result in permanent disability. Eighteen out of 62 (29.03%) subjects experienced a procedure-related AE in the "PHIL dAVF" study and of those 18 subjects, 22 events were observed. None of the procedure-related AEs resulted in mortality or permanent morbidity, except for one non-neurological procedure-related SAE (1.6%), failure to thrive, that resulted in death of the patient.

Table 12. Secondary Measured Outcomes

Secondary Measured Outcome	n/N (%)[+] [# Events]
Neurological death or ipsilateral stroke within the first 30 days following completion of all PHIL treatments	0/62 (0.00%)
Angiographic occlusion of the pre-specified target vessel intended for treatment at procedure following completion of all PHIL treatment procedures[*]	60/62 (96.77%)
New onset or worsening of permanent morbidity at 6 months	0/62 (0.00%)
New onset of intracranial hemorrhage at 6 months	0/62 (0.00%)
New onset of cranial nerve palsy at 6 months	1/62 (1.61%)
Clinically significant technical events during the PHIL embolization procedure(s)**	0/62 (0.00%)
Reflux of embolic material	0/62 (0.00%)
Migration of the embolic material	0/62 (0.00%)
Catheter entrapment	0/62 (0.00%)
Catheter damage	0/62 (0.00%)
Vessel dissection	0/62 (0.00%)
Device-related AEs at procedure and ≤ 30 days	1/62 (1.61%)
Device-related mortality at procedure and ≤ 30 days	0/62 (0.00%)

Secondary Measured Outcome	n/N (%)[+] [# Events]
Procedure-related AEs[$]	18/62 (29.03%) [22]
Complications of arterial puncture	2/62 (3.23%) [3]
Contrast-induced nephropathy	0/62 (0.00%) [0]
Radiation-induced injuries	4/62 (6.45%) [4]
Renal and anesthesia-related complications	6/62 (9.68%) [7]
Other^	7/62 (11.29%) [8]
New onset of device-/procedure-related neurological deficit or AE, or worsening of a previous neurological complaint, disorder, deficit or AE unresolved at 6-month follow-up even if not associated with a change in mRS	0/62 (0.00%)

[+]Rates represent the rate of subjects with events and the number of events, where applicable are shown in brackets
[*]Worst-case analysis occlusion rate reported in the table.
[$]22 events occurred in 18 subjects.
^Other procedure-related AEs included headaches, non-clinically significant vasospasm, neck soreness, and urinary bleeding.
**Clinically significant technical event is defined as technical event that led to any adverse events.

Additional Outcomes

The number of PHIL procedures required to treat the fistulas in a given patient at 6-month follow-up is shown in Table 13. In addition, information on the adjunctive treatments used in subjects in the study is summarized in Table 14. Throughout the study, adjunctive devices were used in eight subjects including coiling and other (non-PHIL) liquid embolics. Technical events reported in the "PHIL dAVF" study are summarized in Table 15. The three technical events included two cases of migration of embolic material and one case of DMSO syringe malfunction. The observed technical events were not associated with adverse events and were not considered clinically significant by the DSOMC.

Table 13. Number of PHIL Procedures Required to Treat the Fistulas

Number of PHIL Procedures	n/N (%)
1	55/62 (88.7%)
2	6/62 (9.7%)
3	1/62 (1.6%)

Table 14. Adjunctive Treatments

Adjunctive Treatment	n/N (%)
Overall adjunctive treatment	8/62 (12.9%)
Coiling	6/62 (9.7%)
Non-PHIL liquid embolic	2/62 (3.2%)

Table 15. Technical Events

Technical Event	n/N (%)	Did Event Lead to an AE
Migration of embolic material	2/62 (3.2%)	No
DMSO syringe malfunction	1/62 (1.6%)	No

No analyses were performed for any specific subgroups (e.g., based on age, sex, race, ethnicity, or other relevant characteristics) because of the limited sample size of the "PHIL dAVF" study.

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 twenty-three (23) investigators of which none were full-time or part-time employees of the sponsor, and nine (9) investigators had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0
- Significant payment of other sorts: 9 investigators
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 0

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. SAFETY AND PROBABLE BENEFIT ANALYSIS

A. Probable Benefit Conclusions

In the clinical study, following completion of the first PHIL treatment, 96.77% percent of subjects showed occlusion of the pre-specified target vessel as confirmed by the core lab using a worst-case analysis. This result, when evaluated descriptively, demonstrates probable benefit for patients with intracranial dAVFs treated with the PHIL Liquid Embolic System.

Of the 62 subjects in the FAS population, 8/62 subjects (12.9%) required unplanned adjunctive therapies to occlude their dAVFs including coiling [6/62 (9.7%)] and use of non-PHIL liquid embolics [2/62 (3.2%)]. Additionally, of the 62 subjects in the FAS population, the majority of subjects experienced adequate dAVF treatment [55/62 (88.7%)] with a single PHIL procedure, while 6/62 (9.7%) subjects required two procedures, and 1/62 (1.6%) subjects required three PHIL procedures.

B. Safety Conclusions

The risks of the device are based on non-clinical laboratory and animal studies as well as data collected in the "PHIL dAVF" clinical study to support HDE approval as described above.

None of the subjects in the FAS analysis population experienced a primary safety event defined as neurological death or ipsilateral stroke within the first 30 days following completion of the first PHIL treatment procedure as adjudicated by the DSOMC. No primary safety outcome events were observed through the 6-month follow-up period. There were no technical events of embolic material reflux, embolic material migration, catheter entrapment, catheter damage, or vessel dissection that led to AEs. The "PHIL dAVF" study had 2 subjects who experienced embolic material migration [2/62 (3.2%)] and one subject who experienced DMSO syringe malfunction [1/62 (1.6%)]. Eighteen (18) of 62 subjects in the FAS population experienced a procedure-related AE (29.03%) and 1 subject experienced a device-related AE of facial paralysis [1/62 (1.6%)] that did not result in permanent morbidity. One non-neurological procedure-related SAE (1.6%), failure to thrive, resulted in death of the patient.

C. Probable Benefit-Risk Conclusions

The probable benefits of the device are also based on data collected in a clinical study conducted to support HDE approval as described above. The clinical study supported that the device can be used to obtain angiographic occlusion of the pre-specified target vessel(s) immediately post-procedure and was shown to have probable benefit in best- and worst-case analysis scenarios.

The probable risks of the device are also based on data collected in a clinical study conducted to support HDE approval as described above. Adverse events attributable to the device in the study were limited to a single instance of facial paralysis occurring in one (1) subject. No subjects experienced a primary safety outcome event of neurological death or ipsilateral stroke following completion of all PHIL treatment procedures throughout the duration of the clinical study.

Additional factors to be considered in determining probable risks and benefits for the PHIL Liquid Embolic System included:

- Consideration of limited alternative options available for patients with dAVF.

- Probable benefit is based on evaluation of treatment of a pre-determined vessel rather than the overall dAVF which introduces moderate uncertainty in the probable benefit of the device.
- The complete occlusion (100%) of the entire dAVF was not evaluated post-operative; therefore, the long-term stability of the PHIL embolization procedure is unknown nor whether patients require further retreatment.
- The duration of follow-up is limited to 6-months, which does not address the potential for recanalization of dAVF at longer time points. A lack of longer-term data introduces some additional uncertainty regarding the probable benefits and risks, as subsequent recanalization may necessitate additional treatments, or result in additional AEs.

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 HDE for this device.

In conclusion, given the available information above, the data support that for the treatment of intracranial dAVFs the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and probable benefit of this device when used in accordance with the indications for use. The patients who were analyzed as part of the clinical study showed meaningful probable benefit with complete angiographic occlusion of the pre-specified target vessel within the dAVF following completion of the first PHIL treatment procedure and all necessary subsequent PHIL treatment procedures. The safety of the device was demonstrated through a low rate of device-related adverse events.

Therefore, it is reasonable to conclude that the probable benefit to health from using the device for the target population outweighs the risk of illness or injury, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment when used as indicated in accordance with the directions for use.

XIII. PANEL RECOMMENDATION

This HDE was not taken to a meeting of the Neurological Devices Panel because the results of the clinical study support the potential for probable benefits that outweigh the risks in the intended patient population. Furthermore, the non-clinical information supports that the device is comparable to other neurovascular liquid embolic devices in terms of device safety, and the information provided in this HDE did not raise any unanticipated safety concerns.

XIV. CDRH DECISION

CDRH has determined that, based on the data submitted in the HDE, the PHIL Liquid Embolic System will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from using the device outweighs the risks of illness or injury. CDRH issued an approval order on December 31, 2025.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATIONS

Directions for use: See the device labeling.

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

Post-approval Requirements and Restrictions: See approval order.