SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Sealant, Dural

Device Trade Name: Adherus AutoSpray Dural Sealant
Adherus AutoSpray ET Dural Sealant

Device Procode: NQR

Applicant's Name and Address: Stryker Leibinger GmbH & Co.KG
1941 Stryker Way
Portage, MI 49002

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P130014/S022

Date of FDA Notice of Approval: July 15, 2026

The original PMA (P130014) for the Adherus AutoSpray Dural Sealant was first approved on March 30, 2015, and the Adherus AutoSpray Extended Tip (ET) Dural Sealant (P130014/S002) was approved on August 2, 2016 as a product line extension. Both devices were originally indicated for use in patients 13 years of age and older, as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during cranial procedures. The SSED to support the indication is available on the following FDA website and is incorporated by reference herein:
https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130014B.pdf

The current supplement was submitted to expand the indications for use of the Adherus AutoSpray Dural Sealant and Adherus AutoSpray Extended Tip (ET) Dural Sealant to include use during spinal procedures.

II. INDICATIONS FOR USE

The Adherus AutoSpray Dural Sealant and Adherus AutoSpray ET Dural Sealant are indicated for use in patients who are 13 years of age and older, as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during cranial and spinal procedures.

III. CONTRAINDICATIONS

The Adherus AutoSpray Dural Sealant and Adherus AutoSpray ET Dural Sealant devices should not be used in confined anatomical spaces where nerve compression is of concern.

The hydrogel may swell by up to 13% of its size in any dimension or 46% by volume after application.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Adherus AutoSpray Dural Sealant / Adherus AutoSpray ET Dural Sealant labeling.

V. DEVICE DESCRIPTION

Hydrogel:

The Adherus AutoSpray Dural Sealant and Adherus AutoSpray ET Dural Sealant (Adherus AutoSpray) are surgical sealant that polymerizes to form a hydrogel film when sprayed onto the surgical site. The Adherus AutoSpray system consists of components for preparation of a completely synthetic, absorbable sealant and a pre-assembled applicator for delivery of the sealant to the target site. The Adherus AutoSpray is composed of two solutions, a polyethylene glycol (PEG) ester solution and a polyethylenimine (PEI) solution (referred to as the "green" and "clear" precursors, respectively). When mixed together, the precursors cross-link and form the surgical sealant. The mixing of the sealant precursors is accomplished within and immediately prior to exiting the applicator nozzle, where the two solutions are thoroughly mixed and delivered to the target site in a tight spray pattern. The Adherus AutoSpray is absorbed by the body over approximately 90 days, during which time the dural surface heals.

Applicator:

The Adherus AutoSpray Applicator is a sterile, single-use electromechanical, battery-operated device with internal system components that provide air flow to aid in the delivery of a synthetic, absorbable two-component hydrogel sealant system. The device is supplied as a pre-assembled applicator with a standard spray nozzle or an Extended Tip (ET) nozzle, and two separate glass vials (Figure 1 and Figure 2).

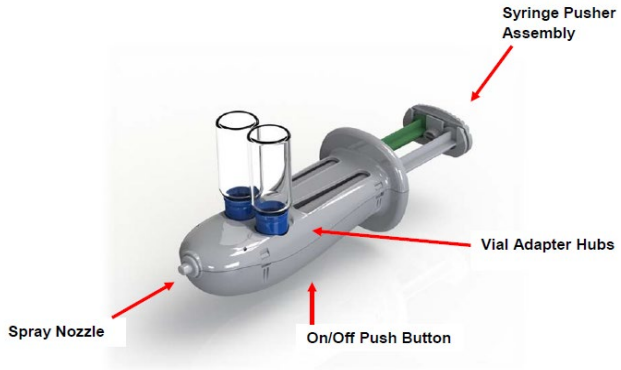

Figure 1: Adherus AutoSpray Dural Sealant Applicator

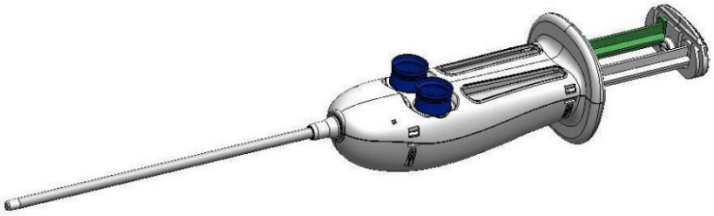

Figure 2: Adherus AutoSpray Extended Tip (ET) Dural Sealant Applicator

The Adherus AutoSpray Applicators are comprised of the following primary components:

Spray Nozzle:

The spray nozzle on the Adherus AutoSpray Applicator functions by mixing the two reconstituted solutions and delivers the mixed solution to the target site through a tight spray pattern. The spray nozzle is attached to the system and is not removable. The Extended Tip (ET) Applicator includes a longer malleable tip nozzle which functions similarly to the spray nozzle and may be bent or shaped to preference.

Vial Adapter Hubs:

The vial adapter hubs, located on the top of the housing, connect to the vials containing the crosslinking components of the Adherus AutoSpray.

On/Off Push Button Switch:

An On/Off switch is located on the bottom of the Applicator housing which turns the battery-operated air pump on and off. The device is shipped with the switch in the OFF position, which isolates the air pump from the battery power source. At the time of formulation delivery, the switch is depressed, putting the switch into the ON position and turning on the air pump.

Battery Removal Door:

On the underside of the housing is a door which allows the Operating Room (OR) staff to remove the batteries (two AAA) for appropriate disposal after the device is used. The battery door is glued shut. A flat instrument can be used to pry the battery door open and remove the batteries for disposal.

Syringe Pusher Assembly:

The syringe pusher assembly mechanically locks the two syringe plungers such that advancement of both syringe plungers occurs simultaneously.

The operating procedure for the Adherus AutoSpray can be found in the Instructions for Use.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives to provide watertight dural closure during spinal procedures including suture closure, use of other approved dural sealants, use of dural replacement materials (duraplasty) for covering significant dural gaps, adhesives, and hemostatic agents. 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 their unique individual patient needs.

VII. MARKETING HISTORY

The Adherus AutoSpray is marketed in the following countries: Austria, Australia, Belgium, Bulgaria, Brazil, Canada, Croatia, Denmark, France, Finland, Germany, Greece, Italy, Ireland, Japan, Netherlands, New Zealand, Norway, Portugal, Russia, Saudi Arabia, South Africa, South Korea, Spain, Switzerland, Taiwan, Turkey, United Arab Emirates, and United Kingdom.

The Adherus AutoSpray has not been withdrawn from marketing in any country due to reasons related to the safety and effectiveness of the device.

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:

- CSF leak including pseudomeningocele
- Adverse surgical site reactions, e.g., infection, meningitis, inflammation, edema
- Neurological complications, e.g., convulsion, dysphagia, meningitis, neurological deficits
- Surgical trauma resulting in hematoma
- Immunological reactions, e.g., allergic reaction, swelling of the face
- Hydrogel swelling resulting in nerve compression

Potential adverse effects associated with the procedure include:

- Allergic reaction
- Blood and lymphatic system disorders
- Cardiac disorders
- Dermatological events
- Gastrointestinal disorders
    - Nausea and/or vomiting
- General disorders
    - Delayed healing
    - Wound dehiscence
    - Chronic pain
- Hematomatologic abnormality
- Hematologic abnormality
- Infections and infestations

    - Deep incisional surgical site infections
    - Superficial surgical site infections
    - Meningitis (aseptic or bacterial)
    - Encephalitis
    - Late incisional surgical site infections
- Inflammatory reaction
    - Arachnoiditis
- Musculoskeletal events
- Neoplasms benign and malignant, including cysts and polyps
- Nervous system disorders
    - Acute gate dysfunction
    - Chronic subdural hematoma and effusion
    - Dural-cutaneous fistula
    - Epidural hematoma
    - Headache
    - Seizure
    - Cerebral hemorrhage
    - CSF leak
    - Double vision
    - Hydrocephalus
    - Cerebral edema
    - Brain tumor
    - Severe neurological deficit post-op
    - Respiratory and thoracic disorders
    - Leakage of cerebrospinal fluid
    - Pseudomeningocele
    - Pneumocephalus
    - Spinal abscesses
- Renal compromise

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

IX. SUMMARY OF PRECLINICAL STUDIES

Refer to the SSED for the original Adherus AutoSpray PMA, P130014, for a summary of preclinical studies. Nonclinical data to evaluate the design change incorporating the Adherus AutoSpray Extended Tip were provided under the original PMA. No additional non-clinical studies were performed in support of the current application.

X. SUMMARY OF CLINICAL STUDIES

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of a dural sealant used in spinal procedures with Adherus AutoSpray for use in patients 13 years of age and older, as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during spinal procedures in the US under

Investigational Device Exemption (IDE) # G190134. The data from this clinical study were the basis for the PMA supplement approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between January 19, 2021, and January 24 2025. The database for this Panel Track PMA Supplement reflected data collected through August 29, 2025, and included 94 subjects. There were 14 investigational sites, all within the United States (US).

The study was a prospective, randomized (1:1), controlled, single-blind, multicenter, pivotal clinical study to compare the safety and effectiveness of Adherus AutoSpray to the Integra LifeSciences DuraSeal Exact Spine Sealant System (DuraSeal, control group) when used in conjunction with standard methods of dural repair in spinal procedures.

The study included an independent medical monitor responsible for review of safety-related events. and the study used an independent Clinical Events Committee (CEC) to adjudicate adverse events regarding severity and relatedness to the device and procedure.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the pivotal study was limited to subjects who met the following criteria:

- Subject is ≥ 18 and ≤ 75 years old.
- Subject is scheduled for an elective spinal procedure that will require a planned durotomy.
- Subject requires a procedure involving a Class I/clean wound (uninfected surgical wound in which no inflammation is encountered).
- Subject is able and willing to provide informed consent and HIPAA authorization.
- Subject is able and willing to meet all study requirements, including attending all post-index procedure assessment visits and radiological tests.
- Subject has durotomy edges that can be re-approximated using the investigator's standard methods of dural repair.

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

- Subject has clinically significant hydrocephalus or clinical evidence of altered cerebrospinal fluid (CSF) dynamics.
- Subject has a pre-existing external lumbar CSF drain or internal CSF shunt.
- Subject has experienced previous CSF leak (secondary to trauma, neoplasm, surgery or other etiology).

- Subject is undergoing a Chiari malformation procedure.
- Subject has undergone a previous spinal procedure in the same anatomical location.
- Subject has had radiation treatment to the surgical site, or standard fractionated radiation therapy is planned within ten (10) days post-index-procedure.
- Subject has spinal metallic implants that may cause significant imaging artifact on the MRI evaluation of the spine.
- Subject has metallic implant(s) that are not compatible with magnetic resonance imaging [MRI), e.g., cochlear implant, neurostimulator, stent, surgical clip, cardiac pacemakers, or other non-MRI compatible implants], or an elective implant of such devices is planned during the course of the study. Note: mercury amalgam dental fillings or similar metallic dental prostheses are not an exclusion criterion.
- Subject has a known malignancy or another condition with anticipated survival shorter than six months.
- Subject has undergone chemotherapy treatment, excluding hormonal therapy, within three weeks prior to the planned index procedure, or chemotherapy treatment is planned within two weeks after the index procedure is performed.
- Subject has been treated with chronic steroid therapy (defined as regular (daily) administration of steroid agent(s) for ≥ 8 weeks) unless discontinued greater than four weeks prior to the planned index procedure. Note: standard acute perioperative steroids are permitted; administration of steroid agents for < 8 weeks duration prior to the planned index procedure is permitted.
- Subject has received warfarin, heparin, other anticoagulant agents, aspirin or non-steroid anti-inflammatory agents on a daily basis and pre-surgical, standard of care drug wash-out did not occur.
- Subject has a compromised immune system or autoimmune disease or is on chronic immunosuppressant agents at baseline.
- Subject has a systemic infection or evidence of any infection near planned operative site.
- Subject has a serum creatinine level > 2.0 mg/dL.
- Subject has a serum total bilirubin > 2.5 mg/dL at baseline.
- Subject has uncontrolled diabetes as evidenced by an HbA1c > 7% prior to surgery.
- Subject has a known allergy to FD&C Blue #1 and/or FD&C Yellow #5 or any of the constituents of the dural sealants.
- Subject is pregnant, breast-feeding, or intends to become pregnant during the course of the study.
- Subject is participating in a clinical trial of another investigational drug or device and has not completed the required follow-up period.
- Subject has an incidental finding that meets any pre-operative exclusion criterion listed above.
- Subject's dural defect cannot be closed with suture and/or duraplasty material.

- Subject has a gap > 2 mm present between dural edges, or between the edge of dura and duraplasty material, based on visual estimate by surgeon before application of the surgical sealant.
- Subject had undergone laminoplasty decompression.
- Subject had undergone a syringomyelia procedure where the shunt is not placed in the subarachnoid position.

2. Follow-up Schedule

All subjects were scheduled to return for follow-up examinations at post-operative days 1-3 or hospital discharge (whichever occurred first), 30 days, and 90 days post-index procedure.

Preoperative, intraoperative, and postoperative assessments included physical and neurological examinations, imaging (magnetic resonance imaging (MRI) and/or computed tomography imaging (CT)), laboratory measures, assessment for CSF leak and pseudomeningocele, and assessment of adverse events.

3. Clinical Endpoints

The primary endpoint was the success rate defined as freedom from the following events:

- CSF leak or pseudomeningocele diagnosed by physical examination, biochemical assay or imaging through 90-day following the index procedure.
- Unplanned retreatment of the original surgical site, adjudicated as device-related by the CEC, other than CSF leak or pseudomeningocele formation or those related to the subject's pre-existing condition, through 90-day following the index procedure including:
  - treatment for deep infection
  - treatment for meningitis
  - minimally invasive procedures or return to the operating room for neurosurgical complications

The primary endpoint was evaluated as a non-inferiority analysis with a non-inferiority margin (NIM) of 13.0%. The primary hypothesis was defined as follows:

$$H_0: \pi_A \leq \pi_D - \delta$$
$$H_1: \pi_A > \pi_D - \delta$$

where π_A is the success rate of Adherus AutoSpray, π_D is the success rate of DuraSeal (control) and δ is the non-inferiority margin equal to 13%. As part of the decision-making process for the subject PMA, FDA did not consider a NIM of 13% to be acceptable and evaluated the safety and effectiveness profile of the Adherus AutoSpray based on the results of the clinical study. The primary

endpoint was evaluated using a one-sided normal approximation (z-test) for comparing two proportions as a 0.05 significance level.

Individual patient success was defined as those experiencing freedom from the primary composite endpoint. With regard to success/failure criteria of the study, the study was considered a success if the null hypothesis for the primary endpoint was rejected at a one-sided 0.05 significance level demonstrating non-inferiority of the Adherus AutoSpray to the DuraSeal when considering the primary endpoint.

B. Accountability of PMA Cohort

At the time of database lock, of the 94 subjects enrolled in the study, 82 (87.2%) subjects (44 in the Adherus AutoSpray (test) group and 38 in the Duraseal (control) group) had data available for analysis at the 90-day postoperative visit. A total of four subjects withdrew from the study prior to the 90-day endpoint, two in the test group and two in the control group. Additionally, two patients were lost to follow-up (one in each group), and two subjects exited the study for other reasons (one subject in the test group and one subject in the control group, both due to administrative errors at the investigational sites). One control subject missed the 90-day follow-up visit. One patient death occurred at day 43 in the test group, for reasons unrelated to the device. Figure 3 presents subject disposition at each follow up visit.

The following analysis populations were defined in the protocol and Table 1 reports the number of subjects in each population.

Intent-to-Treat (ITT): This analysis population includes all randomized subjects and will be analyzed per the assigned treatment, regardless of actual treatment received. The primary analysis will be conducted using the ITT population.

Per-Protocol (PP): This analysis population includes all subjects who receive the treatment to which they were randomized and without protocol deviations that could impact the study outcomes.

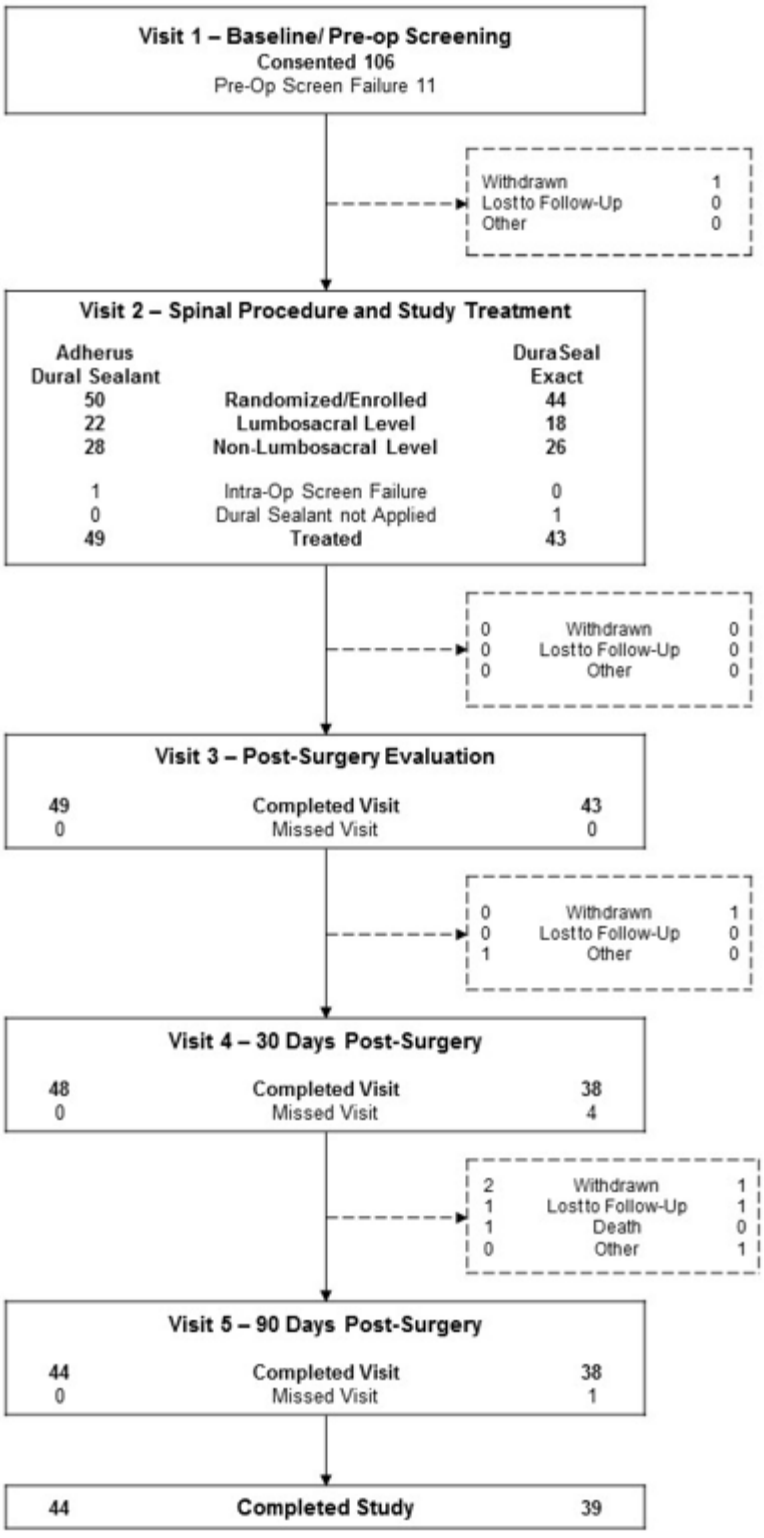

Figure 3: Subject Disposition

Table 1: Number of Subjects by Analysis Population

Study Population	Test Group	Control Group	Total
Enrolled / Randomized	50	44	94
ITT (Intent to treat)	49	43	92
PP (Per protocol)	41	35	76
Completed	44	39	83

C. Study Population Demographics and Baseline Parameters

The demographics and baseline characteristics of the study population are typical for a dural sealant study performed in the US as shown in Table 2. The treatment arms were generally well balanced while the control group was generally older and some differences existed when considering the reason for surgery.

Table 2: Subject Demographics and Spinal Surgery History

Characteristics	Test Group	Control Group
Number of Subjects	50	44
Men/Women	22/28	25/19
Median Age (years)	54.1	61.6
Ethnicity:		
Hispanic or Latino	6/50 (12.0%)	4/44 (9.1%)
Not Hispanic or Latino	41/50 (82.0%)	38/44 (86.4%)
Unknown or Not Reported	3/50 (6.0%)	2/44 (4.5%)
Race (not mutually exclusive):		
American Indian or Alaska Native	0/50 (0.0%)	0/44 (0.0%)
Asian	4/50 (8.0%)	2/44 (4.5%)
Black or African American	1/50 (2.0%)	5/44 (11.4%)
Native Hawaiian or Other Pacific Islander	0/50 (0.0%)	0/44 (0.0%)
White	40/50 (80.0%)	32/44 (72.7%)
Other	3/50 (6.0%)	2/44 (4.5%)
Unknown or Not Reported	4/50 (8.0%)	3/44 (6.8%)
Primary Indication for Surgery		
Intradural Tumor	41/49 (83.7%)	32/44 (72.7%)
Intradural Lesion	5/49 (10.2%)	6/44 (13.6%)
Tethered Cord	0/49 (0.0%)	1/44 (2.3%)
Vascular Malformations	0/49 (0.0%)	3/44 (6.8%)
Arachnoid Cysts	2/49 (4.1%)	1/44 (2.3%)
Syringomyelia	0/49 (0.0%)	0/44 (0.0%)
Other	1/49 (2.0%)	1/44 (2.3%)
Anatomical Location		
Lumbar or Lumbosacral	21/49 (42.9%)	18/44 (41.9%)
Cervical or Thoracic	28/49 (57.1%)	25/44 (58.1%)

Characteristics	Test Group	Control Group
Approach		
Anterior	1/50 (2.0%)	1/44 (2.3%)
Dorsal	40/50 (80.0%)	36/44 (81.8%)
Lateral	0/50 (0.0%)	0/44 (0.0%)
Other	9/50 (18.0%)	7/44 (15.9%)
History of Spinal Surgery	7/50 (14.0%)	5/44 (11.4%)
Primary closure technique		
Suture	36/49 (73.5%)	31/44 (70.5%)
Suture + autologous dural material	0/49 (0.0%)	1/44 (2.3%)
Suture + non-autologous dural material	12/49 (24.5%)	11/44 (25.0%)
Other	1/49 (2.0%)	1/44 (2.3%)

D. Safety and Effectiveness Results

1. Primary Endpoint Analysis

The primary composite endpoint analysis was defined as freedom from CSF leak or pseudomeningocele and freedom from unplanned retreatment of the original surgical site through 90 days post index procedure as defined in section A.3 above.

The primary composite endpoint rate was 93.9% for the test group and 91.8% for the control group based on the ITT population and using multiple imputation to impute missing data (Table 3). Since the lower bound of the 90% confidence interval for the difference in the primary endpoint event rate exceeded the non-inferiority margin of -13%, the primary composite endpoint was met (p = 0.004).

Component level data for the primary endpoint is shown in Table 3 indicating that treatment groups generally performed similarly when considering each component.

Table 3: Primary Composite Endpoint Results and Component-Level Outcomes (ITT)

Primary Composite Endpoint	Test Group (N=49)	Control Group (N=43)	Difference (Test - Control)
Composite Endpoint Outcome			
Primary composite endpoint success through 90 days post index procedure [3, *]	93.9% (86.8%, 100.0%)[4]	91.8% (83.0%, 100.0%)[4]	2.2% (-7.2%, 11.5%)[5]
P-Value (H0: $\pi_A \leq \pi_D - 13\%$)	--	--	0.004
Component Level Outcomes^			
Freedom from CSF leak or pseudomeningocele through 90 days post index procedure[1, *]	96.5% (90.8%, 100.0%)[4]	91.1% (82.0%, 100.0%)[4]	5.4% (-3.6%, 14.4%)[5]
Freedom from unplanned retreatment of the original surgical site through 90 days post index procedure [2, *]	97.3% (92.2%, 100.0%)[4]	99.8% (97.8%, 100.0%)[4]	-2.5% (-7.1%, 2.1%)[5]

Primary Composite Endpoint	Test Group (N=49)	Control Group (N=43)	Difference (Test - Control)
[1]CSF leak and pseudomeningocele as adjudicated by the CEC. [2]Unplanned retreatment of the original surgical site only includes those adjudicated by the CEC as being for a reason other than CSF leak or pseudomeningocele, as being related to the device, and as being not related to pre-existing conditions. [3]A subject is considered a primary composite endpoint success if they are free from CSF leak and pseudomeningocele and free from unplanned retreatment of the original surgical site (all as defined above) through 90 days post index procedure. [4]Two-sided 95% Confidence interval [5]Two-sided 90% Confidence interval [*]For the primary analysis, subjects that were not assessed for adverse events at the 90-day follow-up visit and did not experience a qualifying CSF leak, pseudomeningocele, or unplanned retreatment of the original surgical site (all as defined above) through 90 days post index procedure had their outcome determined using multiple imputation.			

A supportive analysis using observed data, excluding missing data rather than using multiple imputation, resulted in a primary endpoint analysis of 95.5% (42/44) for the test group and 92.1% (35/38) for the control group. These results are consistent with the primary ITT analysis using multiple imputation. A sensitivity analysis on the PP population similarly demonstrated non-inferiority (94.7% (36/38) test group and 90.9% (30/33) control group, p-value = 0.003), suggesting robustness of the study conclusions.

The sponsor also conducted a tipping point analysis to evaluate the impact of missing data on the primary endpoint conclusion across all possible missing data scenarios. Non-inferiority was maintained in 31 out of 36 scenarios (86.1%), with the failing scenarios clustered around the worst-case scenario, where all missing test group subjects were assumed to be treatment failures and all missing control group subjects were assumed to be treatment successes. These results did not indicate missing data largely impacted study outcomes, further supporting robustness of the study conclusions under most missing data assumptions.

2. Adverse Events

The safety analysis was based on all adverse events (AEs) observed in all patients enrolled in the study through the 90-day post-surgery evaluation. The key safety findings for this study are reported in Table 4. Table 5 provides a listing of all adverse events occurring at a rate greater than 1% observed in the study through 90 days.

The most commonly reported AEs were infection-related events which occurred in similar number between groups (4.0% (2/50) test group and 6.8% (3/44) control group). No deep infections, meningitis, or CSF leaks were reported in either group. There were no AEs due to device deficiencies/malfunctions or Unanticipated Adverse Device Effects (UADEs) in the study.

Serious adverse events (SAEs) occurred more frequently in the test group (20.0%) compared to the control group (15.9%). Twenty-two SAEs were reported across 10 test subjects (20.0%), one was a superficial infection, one was a pseudomeningocele (2.0%, 1/50), and the remaining 20 SAEs were other events (16.0%, 8/50). Eighteen

SAEs were reported in 7 (15.9%) control subjects. Two of these were infections, with the remaining 16 classified as other events (15.9%, 7/44).

SAEs classified as "other" for the test group consisted of events that were neurological, orthopedic, oncological, cardiovascular, gastrointestinal, or urological in nature. SAEs classified as "other" for the control group consisted of the categories above as well as otolaryngolic, pulmonary, immunological, and hepatic.

Of the AEs observed in the test group, six were possibly related to the study device seen in 3/50 subjects (6%), and zero were definitely related to the device. The six events that were possibly related to the test device were all classified as serious.

The control group had three AEs that were possibly related to the device in 3/44 subjects (6.8%) and one non-serious AE was definitely related to the device and occurred in 1/44 subjects (2.3%). One of the three events that were possibly related to the control device was classified as serious

No SAEs for either treatment group were considered definitely related to the device.

Table 4: Overall Incidence of AEs by Seriousness and Relation through 90 days (all enrolled population)

Relatedness	**Test Group n/N (%)**		**Control Group n/N (%)**	
AE Type	**Events**	**Subjects**	**Events**	**Subjects**
All AEs through 90 days	77	20/50 (40.0%)	95	24/44 (54.5%)
All SAEs through 90 days	22	10/50 (20.0%)	18	7/44 (15.9%)
All device related[2] AEs	6	3/50 (6%)	4	4/44 (9.1%)
All device related[2] SAEs	6	3/50 (6%)	1	1/44 (2.3%)
Death[1]	1/50 (4.0%)		0/44 (0.0%)	
Infection	2	2/50 (4.0%)	3	3/44 (6.8%)
Superficial	1	1/50 (2.0%)	1	1/44 (2.3%)
Deep	0	0/50 (0.0%)	0	0/44 (0.0%)
Meningitis	0	0/50 (0.0%)	0	0/44 (0.0%)
other	1	1/50 (2.0%)	2	2/44 (4.5%)
CSF Leak	0	0/50 (0.0%)	0	0/44 (0.0%)
Pseudomeningocele	1	1/50 (2.0%)	3	3/44 (6.8%)
Retreatment of surgical site	0	0/50 (0.0%)	0	0/44 (0.0%)

[1] Deaths were attributed to pre-existing oncological conditions
[2] Device related AEs and SAEs are those that are possibly or definitely related to the device

Table 5: Adverse Events through 90 days (treated population)

Adverse Event	Test Group, n (%) (N=49)	Control Group n (%) (N=43)
Lhermitte's Syndrome	1 (2.0)	0 (0.0)
Weakness - Upper Extremity	2 (4.1)	2 (4.7)
Paresthesia - Upper Extremity	3 (6.1)	2 (4.7)
Pain - Upper Extremity	2(4.1)	1 (2.3)
Swelling - Upper Extremity	1 (2.0)	4 (9.3)
Weakness - Lower Extremity	3 (6.1)	5 (11.6)
Paresthesia - Lower Extremity	3 (6.1)	4 (9.3)
Pain - Lower Extremity	4 (8.2)	0 (0.0)
Swelling - Lower Extremity	3 (6.1)	3 (7.0)
Weakness - Back	3 (6.1)	0 (0.0)
Pain - Back	3 (6.1)	8 (18.6)
Pain - Chest	2 (4.1)	1 (2.3)
Pain - Abdominal	4 (8.2)	2 (4.7)
Death	1 (2.0)	0 (0.0)
Neuropathy	2 (4.1)	0 (0.0)
Wound Dehiscence	3 (6.1)	1 (2.3)
Dizziness	3 (6.1)	0 (0.0)
Headache	1 (2.0)	2 (4.7)
Seizure	1 (2.0)	0 (0.0)
Pulmonary embolism	2 (4.1)	0 (0.0)
Deep Vein Thrombosis (DVT)	2 (4.1)	2 (4.7)
Pseudomeningocele	1 (2.0)	3 (7.0)
Urinary Tract Infection (UTI)	4 (8.2)	2 (4.7)
Cancer recurrence	2 (4.1)	0 (0.0)
Covid 19	1 (2.0)	2 (4.7)
Hyperglycemia	1 (2.0)	2 (4.7)
Hypotension	1 (2.0)	1 (2.3)
Hip Arthroplasty	1 (2.0)	0 (0.0)
Fever	1 (2.0)	1 (2.3)
Constipation	1 (2.0)	1 (2.3)
Incontinence	3 (6.1)	4 (9.3)
Dyspnea	1 (2.0)	2 (4.7)
Seroma	2 (4.1)	2 (4.7)
Leukocytosis	1 (2.0)	2 (4.7)
Traumatic Foley placement	1 (2.0)	0 (0.0)
Oral Thrush	1 (2.0)	0 (0.0)

Adverse Event	Test Group, n (%) (N=49)	Control Group n (%) (N=43)
Postural Orthostatic Tachycardia Syndrome (POTS)	1 (2.0)	0(0.0)
Herniated disk	1 (2.0)	0 (0.0)
Atrial Fibrillation	0 (0.0)	1 (2.3)
Pain - Neck	0 (0.0)	2 (4.7)
Tracheitis	0 (0.0)	1 (2.3)
Spinal cord compression	0 (0.0)	2 (4.7)
Inferior vena cava placement	0 (0.0)	1 (2.3)
Sepsis	0 (0.0)	2 (4.7)
Infection - Systemic/Pulmonary	0 (0.0)	3 (7.0)
Migraine	0 (0.0)	1 (2.3)
Arrythmia	0 (0.0)	1 (2.3)
Urinary retention	0 (0.0)	1 (2.3)
Ileus	0 (0.0)	1 (2.3)
Anemia	0 (0.0)	1 (2.3)
Hypocalcemia	0 (0.0)	1 (2.3)
Hypomagnesemia	0 (0.0)	1 (2.3)
Hypokalemia	0 (0.0)	1 (2.3)
Epistaxis	0 (0.0)	1 (2.3)
Memory loss/confusion	0 (0.0)	2 (4.7)
Elevated hemidiaphragm	0 (0.0)	1 (2.3)
Cerumen impaction	0 (0.0)	1 (2.3)
Gastritis	0 (0.0)	1 (2.3)
Pleural effusion	0 (0.0)	1 (2.3)
Atelectasis	0 (0.0)	1 (2.3)
Tachycardia	0 (0.0)	1 (2.3)
Increased lactic acid	0 (0.0)	1 (2.3)
Hypoxemia	0 (0.0)	1 (2.3)
Adrenal insufficiency	0 (0.0)	1 (2.3)
Anemia	0 (0.0)	1 (2.3)
Spinal cord hemorrhage	0 (0.0)	1 (2.3)
Low sodium	0 (0.0)	1 (2.3)
Pedicle fracture	0 (0.0)	1 (2.3)

3. Subgroup Analyses

The sponsor conducted exploratory subgroup analyses to examine whether closure method, (suture or duraplasty) or procedure location (lumbar/lumbosacral vs. other) affect the rate of CSF leak or pseudomeningocele using logistic

regression. The subgroup analyses did not identify heterogeneity of the treatment effect when considering different closure methods or procedure location.

The sponsor also conducted exploratory logistic regression analyses to determine whether additional factors (i.e., sealant volume, procedure type, incision location, and patient demographics) present as potential risk factors of CSF leak or pseudomeningocele. These analyses did not identify statistically different outcomes across the covariates evaluated.

No analyses were performed for sex-, age-, race-, ethnicity-, or any other relevant characteristic- specific subgroups.

4. Pediatric Extrapolation

Data in prior approvals of the Adherus AutoSpray under the PMA (P130014) established a reasonable assurance of safety and effectiveness of the device in adolescent pediatric patients ≥ 13 years of age, and that device safety and performance are expected to be similar among pediatric and adult populations. Further, the existing literature and well-known aspects of spinal physiology throughout development offer consistent evidence to support the inclusion of individuals ages 13 years and older in the intended user population.

E. 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 14 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.

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

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA supplement was not referred to the Neurological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation, because the information in the PMA supplement substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The clinical study demonstrated non-inferior performance of the Adherus AutoSpray to the DuraSeal control with respect to the primary endpoint of freedom from CSF leak or pseudomeningocele and unplanned retreatment of the original surgical site at 90 days. The estimated rate of subjects achieving primary composite endpoint success was 93.9% for Adherus AutoSpray and 91.8% for DuraSeal, with a difference of 2.2% (two-sided 90% CI: -7.2%, 11.5%) yielding p = 0.004. Therefore, the primary endpoint was met. Sensitivity analyses with observed data and a PP population showed similar outcomes demonstrating that the primary analysis was robust.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in clinical studies conducted to support PMA approval as described above. The safety analysis was based on all AEs observed in all patients enrolled in the study through the 90-day post-surgery evaluation. Adverse events occurred in similar types and rates for the test and control device. The most commonly reported AEs were infection-related events which occurred in similar number between groups (4.0% (2/50) test group and 6.8% (3/44) control group). No deep infections, meningitis, or CSF leaks were reported in either group. CSF leak was not observed in either group in the study. Pseudomeningocele was observed in similar rates for the Adherus AutoSpray and DuraSeal devices (1/50 (2.0%) and 3/44 (6.8%), respectively).

While SAEs occurred more frequently in the test group (20.0%) compared to the control group (15.9%), the occurrence of SAEs in both groups were within clinically acceptable/expected rates when considering the patient population and procedure. No SAEs for either treatment group were considered definitely related to the device. Six and one SAEs were considered possibly related to the study device for the test and control devices, respectively.

C. Benefit-Risk Conclusions

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA Supplement approval as described above. The benefits of the device include adjunctively providing watertight closure of the dura during spinal procedures. This benefit was observed as non-inferior performance of freedom from CSF leak or pseudomeningocele and unplanned retreatment of the original surgical site at 90 days with respect to the control.

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

device include infection and pseudomeningocele in addition to other AEs observed in the study as noted in section X.D.2 above.

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 dural closure using the Adherus AutoSpray 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 Adherus AutoSpray when used in accordance with the indications for use.

XIII. CDRH DECISION

CDRH issued an approval order on July 15, 2026.

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.

XIV. 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.