August 21, 2026

Zeus Scientific
Daniel Zweitzig
Vice President of R&D
200 Evans Way
Branchburg, New Jersey 08876

Re: K261466
Trade/Device Name: Alegria Flash MPO
Alegria Flash PR3
Alegria Flash GBM
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MOB, MVJ
Dated: July 20, 2026
Received: July 20, 2026

Dear Daniel Zweitzig:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and
Hematology Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261466

Device Name
Alegria FLASH MPO
Alegria FLASH PR3
Alegria FLASH GBM

Indications for Use *(Describe)*

Alegria FLASH MPO:
The Alegria Flash MPO kit uses chemiluminescent immunoassay (CLIA) technology for the semi-quantitative measurement of IgG antibodies to MPO in human serum. It is intended for use as an aid in the diagnosis of microscopic polyangiitis (MPA) in conjunction with other laboratory and clinical findings. The test must be performed on the Alegria Flash instrument.

Alegria FLASH PR3:
The Alegria Flash PR3 kit uses chemiluminescent immunoassay (CLIA) technology for the semi-quantitative measurement of IgG antibodies to PR3 in human serum. It is intended for use as an aid in the diagnosis of granulomatosis with polyangiitis (GPA) in conjunction with other laboratory and clinical findings. The test must be performed on the Alegria Flash instrument.

Alegria FLASH GBM:
The Alegria Flash GBM kit uses chemiluminescent immunoassay (CLIA) technology for the semi-quantitative measurement of IgG antibodies to GBM in human serum. It is intended for use as an aid in the diagnosis of Goodpasture's Syndrome in conjunction with other laboratory and clinical findings. The test must be performed on the Alegria Flash instrument.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) #: K261466

510(k) Summary

Prepared on: 2026-07-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ZEUS Scientific
Applicant Address	200 Evans Way Branchburg NJ 08876 United States
Applicant Contact Telephone	215-917-4246
Applicant Contact	Dr. Daniel Zweitzig
Applicant Contact Email	dzweitzig@sebia.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Alegria Flash MPO (CL28131); Alegria Flash PR3 (CL28141); Alegria Flash GBM (CL28151)
Common Name	Multiple autoantibodies immunological test system
Classification Name	Test System, Antineutrophil Cytoplasmic Antibodies (Anca)
Regulation Number	866.5660
Product Code(s)	MOB, MVJ (CLASS 2) DEVICE MEASURES ANTIBODY TO GBM

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K040111, K071219	ZEUS AtheNA Multi-Lyte Autoimmune Vasculitis Plus Test System (Product Code: A96101)	MOB

Device Description Summary

21 CFR 807.92(a)(4)

Comprehensive Device Description and Principles of Operation Documentation

The Alegria Flash is an FDA-cleared (K230863, K250408, K250666), fully automated, random access, chemiluminescent, walk-away instrument for clinical laboratories. The system was developed and manufactured non-exclusively for ZEUS Scientific by STRATEC (STRATEC SE, Gewerbestr. 37, 75217 Birkenfeld, Germany).

System Features: Some key features of the instrument are outlined below:

- Throughput of ~120 tests per hour for the ZEUS Alegria Flash.
- Sample bay has a maximum capacity of 72 patient samples with continuous loading.
- The reagent bay has a maximum capacity of 16 ready-to-use reagent cartridges with continuous loading.
- Each reagent cartridge utilizes RFID technology to communicate all cartridge data to the instrument.
- Each reagent cartridge rack accommodates two reagent cartridges; back-to-back.
- Reagent tubes are sealed with Dynamic Cap Sealing (DCS) that includes a plastic membrane and cap that is pushed down by the tip during use to maintain a constant level between the cap and the liquid as reagents are used; minimizing evaporation and liquid adhesion to the tip. The reagents housed in these tubes are the microscopic magnetic beads that are coated with the antigen, the serum diluent buffer and the acridinium ester anti-human IgG conjugate.
- Trigger solutions to produce the chemiluminescent reaction are housed in proprietary, Unique Dispense Cartridges (UDC). The UDC combines a primary package and a dispensing system into a single unit that plugs on to the instrument. Each UDC is a single-use disposable unit that provides enough trigger reagent for approximately 1000 assays. By design, it eliminates the exposure of trigger

reagents to lengths of tubes found in other chemiluminescent analyzers. Please see the images below:
• The system uses disposable tips and Unique Stackable Cuvettes (USC) that are pre-oriented to allow for ease of loading into the instrument (see FIGURE 6 below) and perfect orientation for loading reaction vessels into the instrument carousel.
• The many other features of the instrument and the software are detailed in the User's Manual included with this submission.
• NOTE: The Alegria Flash trigger solutions, assay wash buffer and disposables (tips, cuvettes, reagent containers, cartridge case) are purchased by ZEUS Scientific from Stratec. These items are set up as inventoried items that will be supplied by Stratec, but commercialized in the US by ZEUS Scientific. ZEUS Scientific will supply these components to ZEUS's customers.

Principles of Operation: The Alegria Flash kits for this submission are designed to detect IgG class antibodies against antigen in human sera. These test procedures involve three main steps:
1. Sample diluent, test sera, and antigen-coated magnetic particles are added to a reaction cuvette. During the initial incubation, antibodies present in the serum will bind to the immobilized antigen. The beads are then washed to remove unbound antibodies and other serum components.
2. An acridinium ester-conjugated anti-human IgG solution is then added to the reaction cuvette. During the second incubation, the conjugate reacts with IgG antibodies immobilized on the magnetic particles in step 1. The beads are then washed to remove unbound conjugate.
3. Two trigger solutions are added to the cuvette containing immobilized acridinium ester conjugate, causing a flash chemiluminescence reaction to occur. The light signal released by the chemiluminescence reaction is measured by a photomultiplier within the Alegria Flash analyzer and reported as relative light units (RLU). RLU values are converted to Relative Units (RU) within the software. RU values above a predetermined cutoff are indicative of the presence of antibody to the antigen within the original serum sample.
4. Calibration is handled through the system software. Briefly:
• calibration curves (also standard curves or working curves) are used to compensate the differences between reagent lots, different analyzers and environmental conditions. To generate a calibration curve an assay calibration must be run and validated according to the indications reported in the instructions for use of the assay
• All results are calculated in comparison to a calibration curve.
• The specific reference curve (master curve) for a reagent lot is provided by the vendor of the assay cartridge (see instruction for use of the relevant assay for details). If a new reagent lot is used, this curve must be imported to the system and then adjusted by a calibration before sample results can be calculated.
• The measuring signals of the calibrators allow the shift of all master curve points to a working curve, corresponding with the actual conditions during measurement.
• In case that calibrators and specimen are loaded, assigned and started together by pushing the green button, the scheduling will prioritize the calibrators to be run first and any patient data will be calculated based on that calibration curve.
• In case that the calibration curve is invalid due to missing data points, the patient data will stay in the state "data reduction pending" and the missing (re-)calibrator can be restarted within a one-day timeframe (24 hours) to gain a valid curve. If you have not run additional calibrators until that time, the curve will stay invalid and the patient data will have the results NaN.
• To avoid any conflicts, the calibrators can be run first independent of the patient samples, and the patient samples would be run once a valid curve is obtained. For this case ensure, that no patient samples are already assigned to the assay during the "calibrator run" and that calibrators and patient samples are loaded, assigned and started sequentially.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Alegria Flash MPO kit uses chemiluminescent immunoassay (CLIA) technology for the semi-quantitative measurement of IgG antibodies to MPO in human serum. It is intended for use as an aid in the diagnosis of microscopic polyangiitis (MPA) in conjunction with other laboratory and clinical findings. The test must be performed on the Alegria Flash instrument.

The Alegria Flash PR3 kit uses chemiluminescent immunoassay (CLIA) technology for the semi-quantitative measurement of IgG antibodies to PR3 in human serum. It is intended for use as an aid in the diagnosis of granulomatosis with polyangiitis (GPA) in conjunction with other laboratory and clinical findings. The test must be performed on the Alegria Flash instrument.

The Alegria Flash GBM kit uses chemiluminescent immunoassay (CLIA) technology for the semi-quantitative measurement of IgG antibodies to GBM in human serum. It is intended for use as an aid in the diagnosis of Goodpasture's Syndrome in conjunction with other laboratory and clinical findings. The test must be performed on the Alegria Flash instrument.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use are not identical; however, the predicate is older and the IU is not as specific since it is a multiplex immunoassay. While the wording may differ slightly, the intent is that the Indications for Use are the same.

Technological Comparison 21 CFR 807.92(a)(6)

The two devices are both immunoassays designed to capture antibody to autoantigens from human serum. The investigational products are built with chemiluminescence as the detection method. The predicate product is a Luminex (fluorescent) based product. While the detection chemistry may be different, essentially these products are all built in a similar fashion and work in a similar way.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following is a list of the non-clinical studies/investigations conducted in support of this 510(k) submission:
5-day multi-instrument reproducibility study
20-day repeatability study
5-day multi-lot reproducibility study
Calibration frequency study
Carry over study
Establishment of the cut off study
Interference study
LoB/LoD/LOQ Study
Linearity Study
Method comparison study
On-board reagent stability study
Open calibrator vial stability investigation
Open assay cartridge stability investigation
Real time kit stability study
Reference range study
Serum sample freeze-thaw study
Serum sample stability study
Transportation study
CDC and CAP Panel Testing
Analytical Measuring Interval (AMI) report

The sensitivity cohorts consisted of serum samples derived from patients diagnosed with various types of Vasculitides, such as Granulomatosis with polyangiitis (GPA), Microscopic polyangiitis (MPA), and Goodpasture's Syndrome (GS). These samples were provided by Dr. Mark Little, Trinity College Dublin. The specificity cohort consisted of serum samples derived from donors diagnosed with various 'non-Vasculitis' disorders, as well as Vasculitides not associated with ANCA.
A detailed summary of the disease categories and the number of specimens per category has been summarized in the Clinical Study Report and associated Excel sheets attached within this eStar. Ultimately, data from 601 samples were assessed for clinical sensitivity and specificity for the three Alegria FLASH assays referenced in this submission.

A breakdown of the disease categories associated with the 601 samples is as follows:

Microscopic polyangiitis 123
Granulomatosis with polyangiitis 90
Goodpasture's Syndrome 46
Asthma/COPD 30
Chronic Kidney Disease 30
Crohns Disease 20
Graves Disease 20
Hashimoto's 22
HBV 10
HCV 10
HIV 10
Multiple Myeloma 20
Myositis 30
Non-AAV (Giant Cell Arteritis) 20
Rheumatoid Arthritis 20
Sinusitis/Rhinitis 30
Systemic Lupus Erythematosus 30
Systemic Sclerosis 20
Ulcerative Colitis 20

Age and Gender Summary:
- There were 254 male, 346 female, and 1 with gender unknown or not reported.

- The mean age was 57.3, the median age was 58, the minimum age was 9, and the maximum age was 95.

Ethnicity Summary:
- African American, 33
- Asian, 53
- Caucasian, 440
- Hispanic, 25
- Moroccan, 1
- Mixed, 5
- Not listed or Other, 44

The analytical and clinical data provided in this 510(k) submission support a determination that these devices are substantially equivalent to the corresponding predicate devices.