



November 19, 2025

Cytovale, Inc.  
Sarah Esterquest  
Director, Regulatory Affairs  
2 Tower Place  
18th Floor  
South San Francisco, California 94080

Re: K250912

Trade/Device Name: IntelliSep Test  
Regulation Number: 21 CFR 866.3215  
Regulation Name: Device To Detect And Measure Non-Microbial Analyte(s) In Human Clinical Specimens To Aid In Assessment Of Patients With Suspected Sepsis  
Regulatory Class: Class II  
Product Code: QUT  
Dated: March 21, 2025  
Received: March 27, 2025

Dear Sarah Esterquest:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bryan M. Grabias -S

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Bryan Grabias, Ph.D.

Acting Branch Chief

Bacterial Respiratory and Medical Countermeasures Branch

Division of Microbiology Devices

OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K250912

Device Name  
IntelliSep Test

### Indications for Use (Describe)

The Cytovale IntelliSep test is a semi-quantitative test that assesses cellular host response via deformability cytometry of leukocyte biophysical properties and is intended for use in conjunction with clinical assessments and laboratory findings to aid in the early detection of sepsis with organ dysfunction manifesting within the first 3 days after testing. It is indicated for use in adult patients with signs and symptoms of infection who present to the Emergency Department. The test is performed on an EDTA anticoagulated whole blood sample.

The IntelliSep test generates an Intel Ii Sep Index value that falls within one of three discrete interpretation bands based on the probability of sepsis with organ dysfunction manifesting within the first three days after testing. The IntelliSep test represents the probability of the clinical syndrome of sepsis and is intended to be used alongside other clinical information and clinical judgment. It does not identify the causative agent of infection and should not be used as the sole basis to determine the presence of sepsis. The IntelliSep test is intended for in vitro diagnostic use.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**1. 510(k) Owner/Submitter Information**

Name: Cytovale, Inc.  
 Address: 2 Tower Place, 18<sup>th</sup> Floor, South San Francisco, CA 94080  
 Telephone: 1-415-417-2188  
 Contact Person: Sarah Esterquest  
 Email Address: sarah.esterquest@cytovale.com

**2. Date Summary Was Prepared**

30 Oct 2025

**3. Device Name and Classification**

Trade Name: IntelliSep test  
 Instrument Name: Cytovale System  
 Classification: Class II (Special Controls)  
 Classification Name: Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis (21 CFR 866.3215)  
 Product Code: QUT  
 Panel: DMD – Division of Microbiology Devices  
 Submission Type: Traditional

**4. Predicate Device Information**

Predicate Product	510(k) Number	Date of Clearance	Classification	Regulation	Classification Product Code
IntelliSep test	K220991	December 20, 2022	Class II (Special Controls)	866.3215	QUT

*Table 1: Predicate device information*

This 510(k) describes modifications made to the IntelliSep Cartridge and its packaging. These modifications are described in Section 8.

**5. Device Description**

The Cytovale IntelliSep test is a short turn-around time (STAT) test, producing results in 10 minutes or less, to aid in the early detection of sepsis with organ dysfunction manifesting within the first 3 days after testing. It assesses the state of immune activation in patients with signs and symptoms of infection who present in the Emergency Department (ED).

The IntelliSep test is run on the Cytovale System, a laboratory benchtop analyzer depicted in Figure 1 and Figure 2.

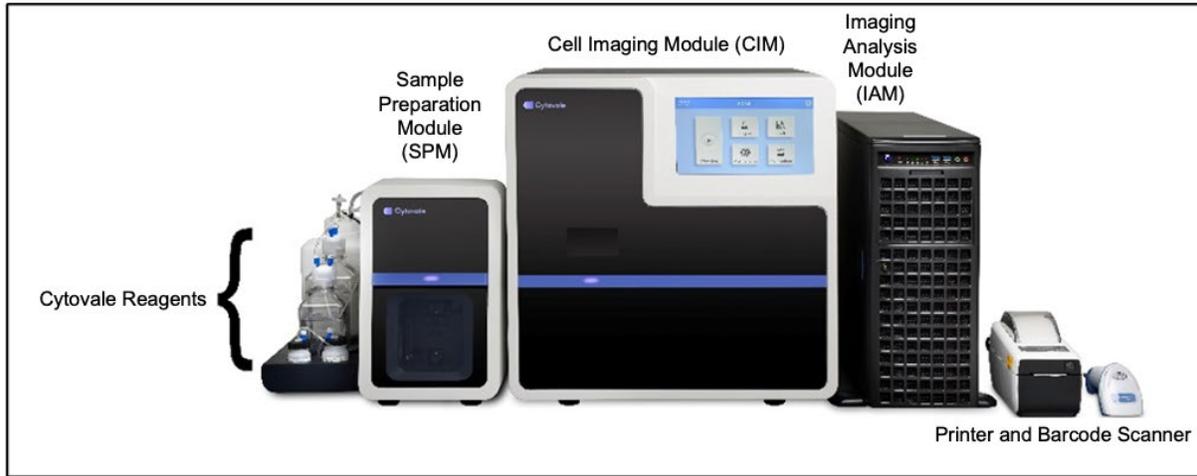


Figure 1: The Cytovale System is a closed system benchtop analyzer, comprised of three modules: Sample Preparation Module, Cell Imaging Module, and Imaging Analysis Module. The original K220991 Imaging Analysis Module is shown in this figure. Also included are the Cytovale System Reagents (Cytovale Reagent Kit, Cytovale Diluent, Cytovale Cleanse), Barcode Scanner and Printer (not shown: IntelliSep Quality Controls, IntelliSep Cartridge, Sample Preparation Tube).

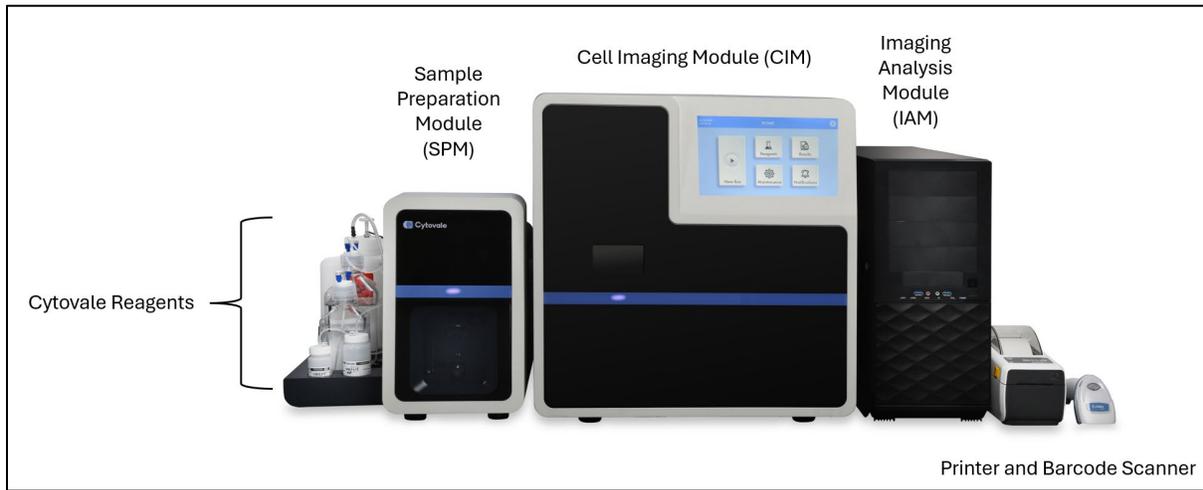


Figure 2: The modified Cytovale System, including an additional Imaging Analysis Module hardware configuration (see K250513). All other Cytovale System materials remain identical to those described in Figure 1 and Table 2.

The IntelliSep test requires use of the materials described in Table 2.

IntelliSep Test Materials & Equipment	Description
Cytovale System: (Required and supplied) <ul style="list-style-type: none"> <li>• Sample Preparation Module (SPM)</li> <li>• Cell Imaging Module (CIM)</li> <li>• Imaging Analysis Module (IAM)</li> </ul>	A closed system benchtop analyzer as shown in Figure 1 and Figure 2. It is comprised of three modules: Sample Preparation Module, Cell Imaging Module, and Imaging Analysis Module.
Barcode scanner (Optional and supplied)	Scanner used to automatically enter sample and material identifiers.

IntelliSep Test Materials & Equipment	Description
Printer (Optional and supplied)	Printer used to print a hard copy of results.
Sample Preparation Tube (Required and supplied)	A single-use, commercial off-the-shelf test tube used for sample preparation.
IntelliSep Cartridge (Required and supplied)	Closed system test cartridge which presents the sample for testing in the Cell Imaging Module.
Cytovale Reagent Kit (Required and supplied)	Nonbiological salt solutions (Reagent A Lysis and Reagent B Quench), for use with the Sample Preparation Module to lyse red blood cells and quench the lysis reaction.
Cytovale Diluent and Cleanse Reagents (Required and supplied)	The Diluent solution is used in the Sample Preparation Module to suspend white blood cells for analysis. The Cleanse is a rinsing solution for the SPM.
IntelliSep Quality Control Kit (Quality controls are required but not supplied)	A two-level Quality Control set, derived from stabilized whole blood.  <i>Note: Per 42 CFR 493.1256, quality controls are required for the IntelliSep test; however, at their discretion, laboratory directors may develop their own quality control materials or order the IntelliSep Quality Control Kit.</i>

Table 2: Materials and equipment required for the IntelliSep test

To run a test, the laboratory operator transfers 100  $\mu$ L of whole blood into the sample preparation tube which is then placed into the Cytovale System. The system automatically lyses red blood cells, and washes the purified leukocytes in a diluent, producing a total volume of approximately 1mL of prepared sample, which the operator then transfers to the IntelliSep cartridge for analysis on the Cytovale System. A microfluidic deformability cytometry technique is used to measure the biophysical properties of thousands of individual leukocytes in rapid succession. These properties have been shown to differ in quiescent white blood cell populations when compared to those in septic patients, enabling rapid assessment of the host response and the likelihood of having sepsis with organ dysfunction manifesting within the first 3 days after testing.

Based on these measurements, the test provides a single score, the IntelliSep Index (ISI), ranging from 0.1-10.0, stratified into three discrete interpretation bands (Band 1, Band 2, Band 3) of increasing sepsis likelihood.

## 6. Intended Use

The Cytovale IntelliSep test is a semi-quantitative test that assesses cellular host response via deformability cytometry of leukocyte biophysical properties and is intended for use in conjunction with clinical assessments and laboratory findings to aid in the early detection of sepsis with organ dysfunction manifesting within the first 3 days after testing. It is indicated for use in adult patients with signs and

symptoms of infection who present to the Emergency Department. The test is performed on an EDTA anticoagulated whole blood sample.

The IntelliSep test generates an IntelliSep Index value that falls within one of three discrete interpretation bands based on the probability of sepsis with organ dysfunction manifesting within the first three days after testing. The IntelliSep test represents the probability of the clinical syndrome of sepsis and is intended to be used alongside other clinical information and clinical judgement. It does not identify the causative agent of infection and should not be used as the sole basis to determine the presence of sepsis. The IntelliSep test is intended for in vitro diagnostic use.

## 7. Indications for Use

See “Intended Use”.

## 8. Overall Comparison Between Subject Device and Predicate

This 510(k) describes modifications made to the IntelliSep Cartridge and its packaging. There were no changes to the intended use or indications for use for the IntelliSep test, nor were there any changes to the underlying technological characteristics or principles of operation of the Cytovale System.

The modifications are described below.

### 8.1. Modifications to IntelliSep Cartridge

The original IntelliSep Cartridge housing (K220991) is constructed of a clear plastic. The modified IntelliSep Cartridge housing is constructed of a different plastic formulation with black colorant. The material of the inlet filter component has also been modified to reduce the likelihood of particulate clogs within the Cartridge.

The critical element of the IntelliSep Cartridge – the microfluidics – are not modified and remain identical to K220991. Similarly, all interface features between the IntelliSep Cartridge and the Cytovale System remain identical to K220991.

Representative images of the original and modified IntelliSep Cartridge are provided below.



Original IntelliSep Cartridge  
(K220991)

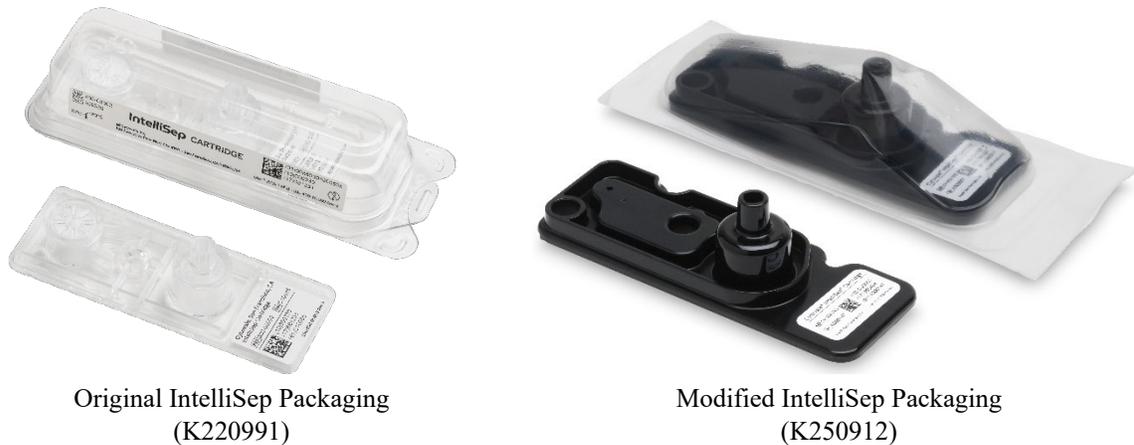


Modified IntelliSep Cartridge  
(K250912)

## 8.2. Modifications to IntelliSep Cartridge Packaging

The original IntelliSep Cartridge packaging (K220991) consists of a two-piece thermoformed clamshell configuration. The modified IntelliSep Cartridge packaging consists of a thermoformed filled and sealed package.

Representative images of the original and modified IntelliSep Cartridge packaging are provided below.



## 9. Non-Clinical and/or Clinical Tests Summary & Conclusions

Verification and validation testing was successfully performed following risk assessment of the device modifications. This testing included the components listed below. No changes to assay performance or device function were observed, and no new risks were identified.

### 9.1. IntelliSep Cartridge Performance Validation

In accordance with the applicable special controls listed in 21 CFR 866.3215, Cytovale confirmed that the modified device maintained identical analytical and clinical performance to the cleared K220991 device.

Identical patient samples were evaluated using the IntelliSep test, using both original, unmodified devices and modified devices. The results of these assay runs (the IntelliSep Indices, or ISIs) were then compared to each other, using analysis methods previously utilized in K220991.

An assessment of overall ISI difference was performed for both septic and not-septic populations, along with an evaluation of assay precision and reproducibility.

No performance differences were observed when using the modified IntelliSep Cartridge; there are no changes to labeled performance claims or limitations when compared to K220991. All performance claims and limitations may be found in the Decision Summary for K220991<sup>1</sup>.

### 9.2. Stability Testing

Both accelerated and real-time stability testing protocols have been established for the modified device component, inclusive of packaging and labeling. Device function, assay performance, and physical package

<sup>1</sup> Available at < [https://www.accessdata.fda.gov/cdrh\\_docs/reviews/K220991.pdf](https://www.accessdata.fda.gov/cdrh_docs/reviews/K220991.pdf) >

and label integrity are monitored and trended per these protocols. Protocol data collection and analysis methods are identical to K220991.

Eight (8) months of real-time stability data have been collected, with further time points in progress. The Cartridge expiry date may be extended upon successful completion of these additional time points.

### **9.3. Shipping Validation**

The modified primary package for the IntelliSep Cartridge was evaluated for integrity after simulated shipping and conditioning per recognized consensus standard ASTM D4169, *Standard Practice for Performance Testing of Shipping Containers and Systems*, and ISTA 7D, *Thermal Controlled Transport Packaging for Parcel Delivery System Shipment*.

The conditioned Cartridges, their labels, and their packaging were confirmed to be undamaged after conditioning. Similarly, there was no discernible performance difference between conditioned and unconditioned Cartridges in the IntelliSep test.

### **10. Proposed Labeling**

The labeling is sufficient and meets the requirements of 21 CFR Parts 801 and 809, as applicable, and meets the special controls for this device under 21 CFR 866.3215.

### **11. Conclusions**

The submitted information in this 510(k) notification is complete and supports a substantial equivalence determination.