April 30, 2026

Bayesian Health Inc.
Thomas Ford
Regulatory & Quality Lead
2 River Terrace
New York, New York 10282

Re: K250680
Trade/Device Name: Bayesian Health Sepsis Flagging Device
Regulation Number: 21 CFR 880.6316
Regulation Name: Software Device To Aid In The Prediction Or Diagnosis Of Sepsis
Regulatory Class: Class II
Product Code: SAK
Dated: April 27, 2026
Received: April 27, 2026

Dear Thomas Ford:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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); 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 Management System Regulation (QMSR) (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,

SIVAKAMI VENKATACHALAM -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.

Submission Number *(if known)*

K250680

Device Name

The Bayesian Health Sepsis Flagging Device

Indications for Use *(Describe)*

The Bayesian Health Sepsis Flagging Device is a continuously monitoring artificial intelligence and machine learning-based software as a medical device intended for use by Health Care Providers (HCPs) in conjunction with clinical assessments and other laboratory data to aid in the early detection and/or risk prediction of sepsis developing within 24 hours.

The Bayesian Health Sepsis Flagging Device uses a machine learning algorithm to analyze patient data from the EHR, which includes a combination of patient information, comorbidities, the chief complaint documented at presentation to the emergency department, laboratory measurements and vital signs, and procedures, medications, and consult orders. The Bayesian Health Sepsis Flagging Device outputs a flag ("Sepsis Risk High") that is displayed within the EHR but should not be used as the sole basis to determine the presence of sepsis or risk of developing sepsis within 24 hours.

The Bayesian Health Sepsis Flagging Device is intended to be used for adult patients (≥18 years old) upon Emergency Department (ED) presentation or hospital admission throughout the duration of the patient's stay in acute care settings.

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) Summary
Bayesian Health Sepsis Flagging Device

This summary of 510(k) substantial equivalence is submitted in accordance with the requirements of 21 CFR §807.92:

1. SUBMITTER INFORMATION [807.92(a)(1)]

Submitter Name	Bayesian Health, Inc.
Submitter Address	2 River Terrace New York, NY 10282
Primary Correspondent	Thomas Ford Regulatory & Quality Leader Bayesian Health
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Date Prepared	February 1, 2026

2. DEVICE NAME AND REGULATORY CLASSIFICATION [807.92(a)(2)]

Trade Name	Bayesian Health Sepsis Flagging Device
Regulation Name	Software device to aid in the prediction or diagnosis of sepsis
Product Code	SAK
Regulation Number	21 CFR 880.6316
Regulatory Class	Class II
Review Panel	Gastroenterology/Urology
Submission Type	Traditional 510(k)

3. PREDICATE DEVICE INFORMATION [807.92(a)(3)]

Trade Name	Sepsis Immunoscore
Regulation Name	Software device to aid in the prediction or diagnosis of sepsis
Product Code	SAK
Regulation Number	21 CFR 880.6316
Regulatory Class	Class II
Review Panel	Gastroenterology/Urology
Submission Type	De Novo
De Novo Identifier	DEN230036

510(k) Summary
Bayesian Health Sepsis Flagging Device

4. DEVICE DESCRIPTION [807.92(a)(4)]

The Bayesian Health Sepsis Flagging Device, developed by Bayesian Health, Inc., is continuously monitoring artificial intelligence/machine learning (AI/ML)-based Software as a Medical Device (SaMD) designed to assist healthcare providers in early sepsis detection and/or risk prediction of developing sepsis within 24 hours by analyzing patient data from the electronic health record (EHR).

The Bayesian Health Sepsis Flagging device consists of two main components, as briefly described below:

1) An AI/ML -based sepsis early detection algorithm
   The Bayesian Health Sepsis Flagging device utilizes an artificial intelligence/machine learning-based sepsis prediction algorithm to analyze routinely collected electronic health record (EHR) data. This algorithm identifies patients at risk of having or developing sepsis, allowing healthcare providers (HCPs) to review these findings alongside standard care practices. The model processes data gathered across the hospital, encompassing patients in the emergency department, observation units, general wards, and intensive care units. This broad scope ensures that at-risk patients in various acute care settings are identified efficiently.
2) An application integrated with the EHR (EHR agnostic)
   The Bayesian Health Sepsis Flagging device includes a cloud-based web application seamlessly integrated into the electronic health record (EHR) system. This integration enables healthcare providers (HCPs) to view sepsis risk flags directly within their existing EHR workflow, streamlining the identification and evaluation process.

The application provides detailed information about each flag, including a summary of clinical factors potentially contributing to the patient being flagged for sepsis risk. HCPs can review this information within the Bayesian Health Sepsis Flagging Device interface and incorporate these insights into their clinical decision-making alongside standard care practices.

5. INDICATION FOR USE [807.92(a)(5)]

The Bayesian Health Sepsis Flagging device is a continuously monitoring artificial intelligence and machine learning-based software as a medical device intended for use by the healthcare providers (HCPs) in conjunction with clinical assessments and other laboratory data to aid in the early detection and/or risk prediction of sepsis developing within 24 hours.

The Bayesian Health Sepsis Flagging Device uses a machine learning algorithm to analyze patient data from the Electronic Healthcare Record (EHR), which includes a combination of

patient information, comorbidities, the chief complaint documented at presentation to the emergency department, laboratory measurements and vital signs, and procedures, medications, and consult orders. The Bayesian Health Sepsis Flagging Device outputs a flag ("Sepsis Risk High") that is displayed within the EHR but should not be used as the sole basis to determine the presence of sepsis or risk of developing sepsis within 24 hours.

The Bayesian Health Sepsis Flagging device is intended to be used for adult patients (≥18 years old) upon Emergency Department (ED) presentation or hospital admission throughout the duration of the patient's stay in acute care settings.

The Bayesian Health Sepsis Flagging Device is a prescription-use only device.

6. SUBSTANTIAL EQUIVALENCE COMPARISON

Bayesian Health Sepsis Flagging Device was compared to its predicate device in intended use, indications for use, design, function, and technology and it was demonstrated that they are substantially equivalent. This submission designates Prenosis Inc.'s legally marketed Sepsis ImmunoScore (DEN230036) as the predicate device. Sepsis ImmunoScore (referred to as the "predicate device" in this submission) has been selected due to its similarities in intended use and technological characteristics with the subject device. Both the subject and predicate devices are prescription-only, AI/ML-based software designed to identify patients at risk of having or developing sepsis.

The comparison with the predicate device is based on the intended use, indications for use, general design, technological characteristics and operational principle. A summary of the subject device compared to the predicate device is provided below.

510(k) Summary
Bayesian Health Sepsis Flagging Device

Feature(s)	Subject Device Bayesian Health Sepsis Flagging Device	Predicate Device Sepsis Immunoscore (DEN230036)
Regulatory Classification (Class, FDA Product Code, Regulation & Regulation Description)	Class II SAK 21 CFR 880.6316 Software device to aid in the prediction or diagnosis of sepsis	Class II SAK 21 CFR 880.6316 Software device to aid in the prediction or diagnosis of sepsis
Indication for Use	Bayesian Health Sepsis Flagging Device is a continuously monitoring artificial intelligence and machine learning-based software as a medical device intended for use by Health Care Providers (HCPs) in conjunction with clinical assessments and other laboratory data to aid in the early detection and/or risk prediction of sepsis developing within 24 hours. The Bayesian Health Sepsis Device uses a machine learning algorithm to analyze patient data from the Electronic Healthcare Record (EHR), which includes a combination of patient information, comorbidities, the chief complaint documented at presentation to the emergency department, laboratory measurements and vital signs, and procedures, medications, and consult orders. The Bayesian Health Sepsis Device outputs a flag ("Sepsis Risk High") that is displayed within the EHR but should not be used as the sole basis to determine the presence of sepsis or risk of developing sepsis within 24 hours. The Bayesian Health Sepsis Device is intended to be used for adult patients (≥18 years old) upon Emergency Department (ED) presentation or hospital admission throughout the duration of the patient's stay in acute care settings.	The Sepsis ImmunoScore is an Artificial Intelligence/Machine Learning (AI/ML)-Based Software that identifies patients at risk for having or developing sepsis. The Sepsis ImmunoScore uses up to 22 predetermined inputs from the patient's electronic health record to generate a risk score and to assign the patient to one of four discrete risk stratification categories, based on the increasing risk of sepsis. The Sepsis ImmunoScore is intended to be used in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment for presence of or progression to sepsis within 24 hours of patient assessment. It is intended to be used for patients admitted to the Emergency Department or hospital for whom sepsis is suspected, and a blood culture was ordered as part of the evaluation for sepsis. It should not be used as the sole basis to determine the presence of sepsis or risk of developing sepsis within 24 hours.

510(k) Summary
Bayesian Health Sepsis Flagging Device

Feature(s)	Subject Device Bayesian Health Sepsis Flagging Device	Predicate Device Sepsis Immunoscore (DEN230036)
	The Bayesian Health Sepsis Device is a prescription-use only device.	
Intended User	Licensed healthcare professionals	Licensed healthcare professionals
Form Factor	Software Only with no hardware	Software Only with no hardware
Type of Interpretation	Adjunctive Information	Adjunctive Information
Timeframe of Prediction	Aid in the early detection and/or risk prediction of sepsis developing within 24 hours	Aid in the risk assessment for the presence of or progression to sepsis within 24 hours of patient assessment and blood culture test ordering
Type of Prediction	Continuous prediction within an hour of new data availability in EHR	Not a Continuous prediction (single prediction)
Patient Contact	No	No
Control of life supporting devices	No	No
Patient Population	The device is intended to be used upon ED presentation or hospital admission throughout the duration of the patient's stay in acute care settings for the adult population (≥18 years old). The device has not been validated in pediatric, labor, or maternity care unit patients, patients who have had surgery in the past 90 minutes, or those admitted for trauma who have not been stabilized.	The device is intended to identify patients, who have a blood culture ordered as part of their evaluation for sepsis and who are at risk of having or developing sepsis within the next 24 hours for the adult population (≥18 years old). The device has not been validated in specific inpatient settings such as ICU or Labor and Delivery units.
Inclusion Environment	Intended for any adult patients upon Emergency Department presentation or hospital admission throughout the duration of the patient's stay in acute care settings, regardless of whether sepsis is suspected.	Intended to be used for adult patients admitted to the Emergency Department or hospital for whom sepsis is suspected, and a blood culture was ordered as part of the evaluation for sepsis.
Algorithm Type	Artificial Intelligence/Machine Learning (AI/ML)	Artificial Intelligence/Machine Learning (AI/ML)

510(k) Summary
Bayesian Health Sepsis Flagging Device

Feature(s)	Subject Device Bayesian Health Sepsis Flagging Device	Predicate Device Sepsis Immunoscore (DEN230036)
Inputs	The core inputs include 115 patient parameters from electronic health records (EHR), including patient history, comorbidities, chief complaints, lab results, vitals, procedures, medications, and consult orders	The core inputs include blood culture order and 22 patient parameters utilized include demographic, vital signs, and blood tests (hematology laboratory values, chemistry laboratory values, and sepsis biomarker concentrations).
Output	"Sepsis Risk High" flag displayed in the EHR	Sepsis Patient View ImmunoScore risk score and the risk Stratification category accessible via electronic medical record (EMR) or web interface
Software Level of Concern	Enhanced according to the June 2023 FDA guidance document	Moderate according to the 2005 FDA guidance document

The Bayesian Health Sepsis Flagging Device and Sepsis ImmunoScore share the same intended use, utilizing AI/ML-based software to assist healthcare providers in sepsis prediction. Both devices use validated sepsis biomarkers, including those from published literature and the Sepsis-3 definition. Both devices are adjunctive tools, not standalone diagnostic solutions, and require a prescription. The Bayesian Health Sepsis Flagging Device is substantially equivalent to the Sepsis ImmunoScore (DEN230036, Prenosis Inc.), as both share the same intended use—assisting healthcare providers in sepsis risk assessment through AI/ML-based analysis of EHR data.

The Bayesian Health Sepsis Flagging Device differs from the predicate device with continuous monitoring device, independence from blood culture order, and applicability to all adult hospitalized patients, regardless of whether sepsis is suspected. However, these differences in modifications do not change its intended use, or core functionality compared to the predicate device. These differences do not raise different questions regarding safety and effectiveness of the device. Performance Testing confirms that Bayesian Health Sepsis Flagging Device performs as intended and is substantially equivalent to the predicate device.

7. SUMMARY OF NON-CLINICAL PERFORMANCE DATA [807.92(b)]

7.1 Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of

Premarket Submissions for Device Software Functions." Design traceability confirmed that all requirement tracing is complete from design inputs to verification/validation and that all risk controls are implemented and effective.

Performance of the Bayesian Health Sepsis Flagging Device has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Software verification testing included software code reviews, automated testing, acceptance testing, labeling review and cybersecurity, and data protection, which confirmed that all software requirements are developed as expected. Tests have been performed in compliance with the following recognized consensus standard:

- IEC 62304:2006/A1:2015- Medical device software - Software life-cycle processes

Support for the substantial equivalence of Bayesian Health Sepsis Flagging Device was provided by requirements, verification, risk management and software testing, at the unit, integration, and system levels. Unit and integration tests verify the functionality for individual software parts; and system-level integration tests cover each specified requirement. System level tests were defined with detailed protocols and objective pass/fail criteria and were clearly documented with test execution results for review. Bayesian Health Sepsis Flagging Device passed all unit, integration, and system level testing demonstrating that all requirements were verified and validated.

7.2 Human Factors

Human factors validation testing was conducted on the Bayesian Health Sepsis Flagging Device to assess comprehension and usability of the device for critical device tasks per IEC 62366-1:2015/A1:2020, ANSI AAMI HE75:2009/(R)2018, and FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices". Results of validation testing performed demonstrate that the Bayesian Health Sepsis Flagging Device has been found to be safe and effective for the intended users, uses, and use environments.

7.3 Cybersecurity

A cybersecurity risk analysis and testing were performed on the Bayesian Health Sepsis Flagging Device per FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," and guidelines of "Post market Management of Cybersecurity in Medical Devices." Cybersecurity documentation and testing evidence are provided in this submission to support the determination of substantial equivalence for the Bayesian Health Sepsis Flagging Device.

7.5 Algorithm Performance Testing

Non-clinical performance testing of the algorithm demonstrates that the device performs as intended under anticipated conditions of use. Testing included simulating the impact of

measurement variability on device performance through perturbations to the inputs and evaluating the impact of observed and simulated input feature missingness on device performance. Simulated input missingness studies were used to evaluate the impact of different rates of input feature missingness and feature imputation on model scores and overall device performance.

8. SUMMARY OF CLINICAL PERFORMANCE DATA

The multi-site clinical validation study evaluated 7732 hospital encounters from 7298 unique patients. Patients were adults aged 18 and older in the United States from 3 clinical sites (4 distinct hospitals). This multi-site study included academic, urban, and suburban hospitals with consecutive patient encounters and included a population that was representative of patients and hospital practices across the United States. A multi-tiered adjudication process was composed of two parts: 1) preliminary computer-assisted adjudication and 2) physician adjudication. Computer-assisted adjudication was used to identify encounters that were clearly negative (non-septic) by identifying cases that did not show any signs of infection and sepsis-related organ dysfunction, based on pre-specified criteria identified by infectious disease physicians. Encounters that were not screened clearly negative by computer adjudication were considered possibly septic and underwent physician adjudication to determine final status and onset times when applicable. Physician adjudicators were blinded to the outcome of the preliminary computer-assisted adjudication procedure. The computer-assisted labeling of clearly non-septic encounters was validated using a verification bias analysis, in which a portion of encounters determined to be clearly non-septic by the computer labeler were reviewed by physician adjudicators. The primary objective of the study was to evaluate the efficacy of the Bayesian Health Sepsis Flagging Device for patients at “risk for sepsis high” in the emergency department, intensive care unit, and the ward. To establish substantial equivalence to the predicate, device performance was evaluated within the 24 hours surrounding sepsis onset.

Encounter-level Performance

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were calculated at the encounter level by comparing device flags to computer-assisted labeling of clearly non-septic cases and retrospective physician adjudication of sepsis. Every time a patient presents to the ED or is admitted was considered a unique patient encounter. A true positive encounter was defined as an encounter that received any device flag occurring within 24 hours of adjudicated sepsis onset. A false positive encounter was defined as a non-septic encounter that received at least one device flag. True negative encounters were defined as non-septic encounters that did not receive any device flag. False negative encounters were defined as septic encounters that did not receive a device flag within 24 hours of sepsis onset (flags may have occurred outside of the 24 hours prior to or after sepsis onset). 95% confidence intervals (CIs) were calculated using bootstrap

resampling (10,000 samples) at the subject level. Acceptance criteria for the study were established as the lower bounds of the 95% confidence interval exceeding 80% PPA and 80% NPA at the encounter-level.

Based on 7,732 hospital encounters across four hospitals, the device achieved the following performance at the encounter-level: Encounter-level PPA 79.4% (95% CI 74.2-84.6), encounter-level NPA 89.5% (95% CI 88.8-90.2). No statistically significant differences in performance were observed across demographic subpopulations, including race, gender, age, and ethnicity.

Although the device did not meet the pre-specified acceptance criteria for encounter-level PPA, the totality of device performance, including flag-level performance, was used to establish substantial equivalence to the predicate.

Flag-level Performance:

The device is intended to continually monitor patients during their stay and therefore a patient may have more than one flag for sepsis during their encounter. Therefore, performance was evaluated at the flag-level to characterize the performance of individual flags generated by the device throughout the duration of the study. Every prediction is independently scored and a resulting flag was defined as any instance where a device calculation resulted in a "sepsis risk high" output from the device during an encounter. In total, 1895 flags were generated in the study. Since no flag is generated when the calculation does not meet the threshold for a "sepsis risk high" notification, a flag level NPV was not calculated. PPV is impacted by a number of factors (such as sepsis prevalence). Among the 233 septic encounters, 221 flags were generated in positive encounters during the clinically relevant timeframe (within the 24 hours surrounding adjudicated sepsis onset) and thus were considered true positive flags. False positive flags included any flags on non-septic encounters and flags on septic encounters that were outside of the clinically relevant 24-hour sepsis onset window.

	Sepsis Flagging Device encounter-level PPA	**Sepsis Flagging Device encounter-level NPA**	**Sepsis Flagging Device Flag-level PPV at observed sepsis prevalence [~3%]**
Metric	79.4% (185/233)	89.5% (6715/7499)	11.7%
95% CI	74.2 - 84.6	88.8 - 90.2	10.0-13.2

510(k) Summary
Bayesian Health Sepsis Flagging Device

The totality of evidence supports sepsis risk identification within the 24 hours surrounding onset in the intended use population, which includes allcomers to the Emergency Department, where sepsis prevalence was approximately 3%. This intended use population differs from that of the predicate device, where the observed sepsis prevalence was higher, as the device is intended for use on patients already suspected of sepsis by a physician. Considering this difference in patient population, the flag-level performance of the Bayesian Health Sepsis Flagging device was found to be substantially equivalent to the ImmunoScore.

Post-market Performance Monitoring of Device Performance

A post-market performance management plan was developed to monitor device performance over the market lifetime of the device. The plan outlines procedures for data collection, analysis methods, monitoring relevant device performance characteristics, including encounter-level and flag-level performance, impact assessments including corrective action (if required), and communicating the device's performance to users. If performance degradation is identified, the plan outlines the process for investigating the sources of performance changes between validation and the real-world environment over time and assessing the impact on safety and effectiveness.

9. CONCLUSION [807.92(b)(3)]

Non-clinical verification and validation testing, together with clinical validation, were performed in accordance with applicable FDA guidance documents and relevant special controls to support that the device meets its specified requirements and intended use. Based on the information provided in the 510(k) submission, it was determined that the subject device, Bayesian Health Sepsis Flagging Device, is substantially equivalent to the legally marketed predicate device concerning indications for use, intended use, design, technology, and performance. The subject device raises no new questions related to safety or effectiveness, as compared to the predicate device.