FDA 510(k) Premarket Notification

CLEARED

K250680 Bayesian Health Sepsis Flagging Device

Apr 30, 2026
420 days to decision

K250680 · Product code: **SAK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250680/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software Device To Aid In The Prediction Or Diagnosis Of Sepsis (SAK)
Date received	Mar 6, 2025
Decision date	Apr 30, 2026
Days to decision	420 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bayesian Health, Inc.**
Location	New York, NY, US
Contact	Rachael Weir
Website	https://www.bayesianhealth.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Bayesian Health, Inc. develops real-time clinical intelligence platforms for proactive patient care. The company partners with leading health systems to deliver continuous patient monitoring and early warning capabilities. With a registered facility in New York, Bayesian focuses on surfacing actionable clinical insights to clinicians at scale. The company has received FDA 510(k) clearance from total submission. Bayesian's cleared device falls within the Gastroenterology & Urology category. The company achieved its first and latest clearance in 2026, demonstrating active r...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k250680/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026