

NEWS RELEASE

Intelligent Bio Solutions Submits FDA 510(k) Package for Intelligent Fingerprinting Drug Screening System, Seeking U.S. Market Clearance

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Submission package includes Method Comparison Study, which delivered accuracy above 98%, sensitivity above 94%, and 100% specificity across three independent U.S. clinical sites

NEW YORK, Sept. 09, 2026 (GLOBE NEWSWIRE) -- Intelligent Bio Solutions Inc. (Nasdaq: INBS) ("INBS" or the "Company"), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced the submission of its 510(k) premarket notification to the U.S. Food and Drug Administration (FDA), seeking regulatory clearance of its Intelligent Fingerprinting Drug Screening System (the "System") for detection of the opiate codeine. The submission represents the culmination of data from a structured, multi-study clinical program that the Company has executed throughout 2026, targeting entry into the multi-billion-dollar U.S. drug screening market.

The Company's 510(k) submission package includes a comprehensive body of clinical evidence generated in partnership with Cliantha Research and CenExel Clinical Research, Inc. The clinical studies were conducted in accordance with FDA guidance and International Council for Harmonisation Good Clinical Practice (ICH GCP) standards. Over 18,000 hours of data collection strengthened the submission, resulting in 18 detailed test reports, and supported by more than 170 attachments. In total, more than 15,000 lines of data were generated, analyzed, and compiled into a package that the Company believes represents the most comprehensive body of clinical evidence it has assembled to date.

Key components included:

- Method Comparison Study: demonstrated accuracy above 98%, sensitivity above 94%, and specificity of 100%,

with all specimens independently verified via liquid chromatography-tandem mass spectrometry ("LC-MS/MS") analysis.

- Usability Study: confirmed that the System can be effectively administered by operators with no specialist laboratory knowledge or prior experience, reinforcing its suitability for workplace deployment.
- Interference Study: demonstrated that the presence of everyday substances commonly encountered in workplace environments, including hand creams, alcohol-based products, oils, dirt, and water, does not impact the System's accuracy or codeine specificity, with results confirmed via LC-MS/MS analysis.
- Precision Testing: demonstrated repeatable, reproducible performance across more than 1,600 tests spanning three production runs and three independent sites.
- Cut-off Study: evaluated codeine detection cut-off levels in 40 adult participants, with results compared against an FDA-cleared predicate device and confirmed through LC-MS/MS analysis.
- Cybersecurity & Software Documentation: addressed all cybersecurity review items, with 100% of medium-risk vulnerabilities remediated and all 19 software bill of materials (SBOM) vulnerabilities fully resolved, with independent third-party verification confirming no remaining issues.

These findings collectively demonstrate the System's accuracy, reliability, specificity, and usability, and the Company's capacity to meet the requirements of the FDA 510(k) regulatory pathway.

"For the past 12 months, planning and executing the studies to build a strong body of data to support our submission has been our team's primary goal," said Harry Simeonidis, President and CEO at Intelligent Bio Solutions. "All of this hard work is reflected in our results, and we have great confidence in our 510(k) package."

INBS' drug screening technology is commercially deployed in certain countries outside the U.S. across workplace, law enforcement, and government settings, where the System has demonstrated its value in delivering rapid, non-invasive, and reliable drug screening results. The U.S. drug screening market represents a multi-billion-dollar annual opportunity spanning workplace testing, criminal justice, pain management, law enforcement, and substance abuse treatment. FDA clearance is expected to expand the Company's addressable market beyond Forensic Use Only settings, supporting its broader U.S. commercialization strategy.

About Intelligent Bio Solutions Inc.

Intelligent Bio Solutions Inc. (Nasdaq: INBS) is a medical technology company delivering intelligent, rapid, non-invasive testing solutions. The Company believes that its Intelligent Fingerprinting Drug Screening System will revolutionize portable testing through fingerprint sweat analysis, which has the potential for broader applications in additional fields. Designed as a hygienic and cost-effective system, the test screens for the recent use of drugs commonly found in the workplace, including opiates, cocaine, methamphetamine, and cannabis. With sample

collection in seconds and results in under ten minutes, this technology would be a valuable tool for employers in safety-critical industries. The Company's current customer segments outside the U.S. include construction, manufacturing and engineering, transport and logistics firms, mining, drug treatment organizations, and coroners.

For more information, visit: <https://ibs.inc/>

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, statements regarding Intelligent Bio Solutions Inc.'s ability to successfully develop and commercialize its drug and diagnostic tests, realize commercial benefits from its partnerships and collaborations, secure regulatory clearance or approvals, and timelines to enter the U.S. market, among others. Although Intelligent Bio Solutions Inc. believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, actual results may differ materially from those expressed or implied by such statements. Intelligent Bio Solutions Inc. has attempted to identify forward-looking statements by terminology, including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," and "approximately," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those described in Intelligent Bio Solutions' public filings with the U.S. Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of the date of this release. Intelligent Bio Solutions undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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