



NEWS RELEASE

# Intelligent Bio Solutions Provides Update on FDA 510(k) Clearance Process for Intelligent Fingerprinting Drug Screening System

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NEW YORK, Sept. 17, 2025 (GLOBE NEWSWIRE) -- Intelligent Bio Solutions Inc. (Nasdaq: INBS) ("INBS" or the "Company"), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today provided an update on its FDA 510(k) clearance process for its Intelligent Fingerprinting Drug Screening System.

In December 2024, INBS submitted its 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for review and clearance of its Intelligent Fingerprinting Drug Screening System. As expected, the FDA reviewed and responded with questions by issuing an Additional Information (AI) request in February 2025. This AI request consisted of over 70 items to be addressed by the Company. With the support of specialized FDA consultants and expert third-party partners, INBS responded to the FDA's questions and submitted additional information in August 2025.

The FDA appeared to be satisfied with the majority of responses to the items and has responded with a request for new additional information that requires the Company to resubmit a new 510(k) notification. As a first-of-its-kind device with no comparable cleared or approved sweat-based product currently on the market, the Company's Intelligent Fingerprinting Drug Screening System requires extensive supporting information to validate its performance. The practical feedback received from the FDA is not uncommon for breakthrough technologies.

INBS is in the process of evaluating the FDA's questions and is currently in consultation with its specialized FDA consultants. The Company expects to have an investor update in the next ten days outlining an updated timeline for FDA clearance.

"The FDA's feedback provides constructive clarity on the additional information it requires to advance our

application," said Harry Simeonidis, President and CEO at Intelligent Bio Solutions. "We are confident in the capabilities of our technology, and we remain fully committed to bringing our innovative solution to the U.S. market. We will work to respond to the FDA's additional questions to support validation of our device, in order to resubmit our 510(k) Notification as soon as possible. The progress we have made so far in terms of additional data collected to substantiate the strength of our product throughout this process places us in a strong position as we work toward clearance. Importantly, our international business continues to grow, enabling us to maintain commercial progress globally while pursuing U.S. clearance outside of the Forensic Use Only market."

The Company continues to advance its commercial activities outside the U.S., developing new partnerships and driving sales growth while pursuing further international market penetration.

#### 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, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, Intelligent Bio Solutions Inc.'s ability to successfully develop and commercialize its drug and diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals, among others. Although Intelligent Bio Solutions Inc. believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking 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," "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, included in Intelligent Bio Solutions' public filings filed with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. 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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