Q-linea announces shipment of first IVD-marked ASTar® instrument to the US

Q-linea AB (publ) (OMX: QLINEA) today announces the first shipment of an IVD-marked instrument to the US for evaluation at customer site.

Following the FDA approval of ASTar on April 26, 2024, Q-linea has now begun to ship instruments ready-built for the US market with dedicated software and consumables. The first such instrument has been sent from Uppsala bound for installation at a customer site. Evaluations of the instrument are scheduled to take place over the next several months.

As Jim Kathrein, VP US Commercial Operations for Q-linea, states, "we are seeing growing interest in ASTar. The team has been working hard since our FDA clearance in April to finalize the US-specific software and settings for ASTar. This shipment is another important milestone for Q-linea as we can now place instruments that are immediately ready for clinical use following their evaluation period. We expect to initiate more evaluations over the coming months as labs are increasingly aware of the potential from high-value rapid AST testing for their patients and the benefits to the lab from improved workflow."

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About Q-linea

Q-linea's rapid AST system, ASTar®, accelerates and simplifies the time-sensitive workflows faced during the treatment of patients with bloodstream infections and sepsis. Hospitals use ASTar to vastly reduce the time to optimal antimicrobial therapies and ensure that patients receive the correct treatments sooner — when time matters most. We are helping to create sustainable healthcare, now and in the future, and safeguard the effectiveness of antibiotics for generations to come.
Q-linea is headquartered in Uppsala, Sweden and has regional offices in Italy and the USA, with partnerships worldwide.
ASTar Instrument and ASTar BC G- Consumable kit are CE-IVD marked and FDA 510(k) cleared. For more information, please visit www.qlinea.com

Attachments

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