

Q-linea's ASTar classified as a breakthrough device by the FDA

Q-linea AB (publ) (OMX: QLINEA) today announces that ASTar has received a breakthrough device designation by the U.S. Food and Drug Administration (FDA).

The categorization "breakthrough device" can be assigned to products that are considered to provide a more effective treatment of severe disease states, where there is no comparable equivalent on the market. The categorization is intended to expedite the regulatory review of medical devices so that patients receive faster access to new treatment options.

"This is a true testament to our work at Q-linea developing breakthrough technology with the goal to help save lives. Being classified as a breakthrough device by the FDA is a true milestone per se, but we also see the possibilities of bringing ASTar to the US market faster with a prioritized regulatory review. We are following out plan and are still planning to submit our 510(k) application this spring," said Jonas Jarvius, CEO of Q-linea.

ASTar Instrument and ASTar BC G-Kit already deliver the broadest answer regarding the combination of the number of antibiotics and the number of double dilution steps of each antibiotic, in a single analysis for gram-negative bacteria. The test enables the analysis of gram-negative bacteria, including difficult-to-grow so-called fastidious bacteria, which satisfies the need for rapid and comprehensive results to support optimal treatment decisions.

ASTar Instrument and ASTar BC G- Kit are CE-marked but not FDA 510(k)-cleared and not available for sale in the United States.

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About Q-linea

Q-linea is an innovative infection diagnostics company that primarily develops instruments and disposables for rapid and reliable infection diagnostics. Our vision is to help save lives by ensuring antibiotics continue to be an effective treatment for future generations. Q-linea develops and delivers preferred solutions for healthcare providers, enabling them to accurately diagnose and treat infectious disease in the shortest possible time. The company's lead product ASTar® is a fully automated instrument for antibiotic susceptibility testing (AST), giving a susceptibility profile within six hours directly from a positive blood culture. For more information, please visit www.qlinea.com.

Attachments

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