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Boule Diagnostics receives warning letter closure

Boule Medical (a Boule Diagnostics subsidiary) has received correspondence on February 28, 2020 stating that the Food and Drug Administration (FDA) has completed their evaluation of the firm's corrective actions in response to the Warning Letter dated October 2, 2018. The letter states that based on FDA's evaluation it appears that Boule has addressed the violations contained in the Warning Letter. With this the warning letter has been closed. FDA expects Boule to continue to maintain compliance with the Federal Food, Drug, and Cosmetic Act.

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About Boule Diagnostics AB (publ)

Boule Diagnostics AB is a global diagnostics company that develops, manufactures and markets instruments and consumable products for blood diagnostics. The company serves hospitals, clinics, laboratories and companies within blood diagnostics, in both human and veterinary hematology. The company operates via subsidiaries in Sweden, the USA, Mexico and Russia. The company products are sold globally primarily through distributors, supported by Boule's own local sales and support personnel. The Boule shares are listed on Nasdaq Stockholm since 2011. www.boule.com