U.S. FDA includes Datascope in the Consent Decree

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Background to today's news

U.S. FDA includes Datascope in the Consent Decree

- Datascope is a subsidiary of Getinge, and manufacturer of life-supporting medical devices such as Intra-Aortic Balloon Pumps which are sold globally
- Datascope received a warning letter in 2019 related to findings related to the organization's procedures and processes
- FDA inspection November 2021-January 2022
- Operations not fully in compliance with the existing quality management system and processes
- Conclusion from FDA to include Datascope in the Consent Decree

Consequences from today's news

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- Datascope is enforcing the ongoing actions to address the findings
- Implementing a new operational quality organization with new leadership integrated in the business operations
- Plan for further improvements will be submitted to FDA in January 2023, in accordance with standard procedure
- Costs for Datascope's improvement activities 2018-2022 amount to approx. SEK 500 M
- The additional costs related to improvements going forward are expected to be immaterial
- Datascope's products will continue to be available for customers

Q&A

Forward looking information

This document contains forward-looking information based on the current expectations of the Getinge's management. Although management deems that the expectations presented by such forward-looking information are reasonable, no guarantee can be given that these expectations will prove correct. Accordingly, the actual future outcome could vary considerably compared with what is stated in the forward-looking information, due to such factors as changed conditions regarding business cycles, market and competition, changes in legal requirements and other political measures, and fluctuations in exchange rates.

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