Press Release
20 February 2021 13:35:00 CET

FDA informs that the review of AroCells 510(k) submission will resume at the latest April 15th 2021

AroCell announced today that the US Food and Drug Administration (FDA) has informed that they will resume the review of AroCells 510(k) submission no later than April 15th 2021.

The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) has been actively engaged in responding to the current pandemic caused by a novel coronavirus (SARS-CoV-2) and the associated disease it causes (COVID-19). Due to the on-going national emergency and the large number Emergency Use Authorization (EUA) requests, FDA have received for in vitro diagnostics (IVDs), staff and managers have been reallocated to complete the review of these requests. This has caused a delay in handling of other 510(k) submissions. The review of AroCell´s 510(k) submission will be resumed no later than April 15th 2021.

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About AroCell

AroCell AB (publ) is a Swedish company that develops standardized modern blood tests to support the prognosis and follow up of cancer patients. AroCell's new technology is based on patented methods to measure Thymidine Kinase 1 (TK1) protein concentrations in a blood sample. The TK 210 ELISA test provides valuable information mainly about the condition of cancer patients. This may help clinicians to optimize treatment strategies and estimate the risk of recurrence of tumor disease during the monitoring of the disease. AroCell (AROC) is listed at Nasdaq First North Growth Market with Redeye AB as Certified Adviser: Certifiedadviser@redeye.se, +46 (0)8 121 576 90. For more information; www.arocell.com

This information is information that AroCell is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2021-02-20 13:35 CET.

Attachments

FDA informs that the review of AroCells 510(k)submission will resume at the latest April 15th 2021