FDA Issues Emergency Use Authorization for New and Developing COVID-19 Treatments

As the COVID-19 crisis rages on, innovators in healthcare continue to pour resources into developing tools and technology to address the chasm of unmet medical needs. During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.

Understanding the complex landscape of FDA regulatory requirements is vital to increasing the production and distribution of personal protective equipment (PPE), antibody and diagnostic testing and ensuring healthcare facilities are equipped with enough ventilators.

FDA recently issued several EUA guidance documents which outlines modifications to the indications, claims, functionality, hardware, and software of FDA-cleared non-invasive devices for tracking vital signs including body temperature, blood pressure, and respiratory and heart rates. For example, FDA now permits devices originally only cleared for healthcare settings in the home setting.

It is essential for healthcare innovators to understand the regulatory mechanisms available to them as FDA continues to assess and reform application and approval pathways to address unmet needs during the COVID-19 crisis. Nelson Hardiman serves as a trusted adviser to resource-conscious digital health and medical technology companies, including diagnostic laboratories and manufacturers. Our attorneys assist clients in navigating FDA regulatory policies, guidance documents, and preparing EUA requests for new technologies seeking expedited access to the market.

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