Promotion of Devices Subject to the FDA's COVID-19 Enforcement Policies

The Biden Administration's withdrawal of the Trump Administration's proposal to exempt 84 medical device types from the FDA's premarket notification, or 510(k), requirement, underscores the promotional framework that developers and marketers of these devices are subject to. The Trump Administration proposal included devices critical to combating the COVID-19 public health emergency, ranging from personal protective equipment and ventilators to remote patient monitoring and other types of digital health devices.

Read more about promotional considerations for these devices **here**.