Is it Lawful to Advertise a Device with an Emergency Use Authorization Pending ?

“In recent months, the Food and Drug Administration (FDA) has issued a record number of Emergency Use Authorizations (EUAs) under Section 564 of the Federal, Food, Drug, and Cosmetic Act (FDCA). With a large number also pending, this review pathway is becoming almost common for a wide range of products, predominantly devices, although drugs and biologics are also eligible,” reports Jeffrey K. Shapiro in ***Hyman, Phelps & McNamara’s FDA Law Blog***.

“In this light, some questions of law and policy already settled regarding 510(k) submissions or premarket approval (PMA) applications may need to be re-analyzed to determine if the answer is the same in the EUA context. With the COVID emergency likely to continue for some time, these questions will not soon disappear.”

“The question of whether a company may lawfully advertise a device with an EUA pending (prior to issuance of the EUA)? For more than 40 years, FDA’s policy has been that a device with a 510(k) pending may be advertised (promoted) prior to clearance.”

Read the article.