[Medical Device Alert] DuPont's Upgraded Manufacturing Process Regarding Their Tyvek® Material and Impact on Medical Device Manufacturers

05 10 2015

Medical Device Alert

In an announcement issued by the Food and Drug Administration on October 2, 2015, the agency has determined that the performance of the new Tyvek® material is functionally equivalent to existing Tyvek® material and therefore, it is not necessary for medical device manufacturers to submit a new 510(k) Notice or PMA supplement for the change based on the upgraded manufacturing process of the Tyvek® material.

Read More: DuPont's Upgraded Manufacturing Process Regarding Their Tyvek® Material and Impact on Medical Device Manufacturers

> Read the full article online