Functional Equivalence of Transition Tyvek

October 02, 2015

We are writing to notify you that on the basis of data submitted by DuPont, including testing of the functional performance of the product during medical device sterilization and maintenance of package integrity over time, the FDA has determined that DuPont's new (Transition) Tyvek® products are functionally equivalent to existing (Legacy) Tyvek® products. Tyvek® is used to fabricate sterile barrier systems for an array of medical devices. The new product is manufactured using an upgraded spinning process.

Absent a specific request or notice from FDA or a risk analysis to the contrary, it is not necessary for medical device manufacturers to submit a new 510(k) or PMA supplement for a change solely in packaging from the Legacy Tyvek® to the Transition Tyvek® manufactured using the upgraded spinning process, including both coated and uncoated styles 1073B and 1059B.

In accordance with FDA's device Quality System regulation (21 CFR part 820), manufacturers should:

- Conduct a Risk Analysis to determine if a premarket submission is needed due to a change in risks (e.g., for IVDs – change in performance, cut-offs).
- Implement their change control procedures in accordance with the Quality System regulation, including, but not limited to, evaluation of the impact of this change on packaging and sterilization (if indicated) processes.
- Document activities associated with this change in accordance with the Quality System regulation, including but not limited to, updating the Device Master Record and the rationale for acceptance of Transition Tyvek®.

For additional information about the Tyvek® transition, see DuPont's WWW.AREYOUREADY.TYVEK.COM.

Thank you.

Food and Drug Administration
Center for Devices and Radiological Health