DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66, Room 5447
Silver Spring, MD 20993-0002

DuPont Protection Technologies
c/o Michael H. Scholla, Ph.D.
Global Director, Regulatory and Standards
Chestnut Run Plaza 735/4250-1
974 Centre Road
Wilmington, DE 19805

Dear Dr. Scholla,

FDA has reviewed amendments 1-4 to the Device Master File (MAF) 1920, received from June 2 to August 10, 2015. You have performed testing as outlined in the "*Protocol for Transition of the Medical Device Industry to Tyvek® Manufactured Using an Upgraded Spinning Process*" provided August 15, 2012 and demonstrated that the new (Transition) Tyvek® product is functionally equivalent to existing (Legacy) Tyvek® products. Tyvek® is used to fabricate sterile barrier systems for an array of medical devices. The Transition Tyvek® is available in both coated (1073B) and uncoated (1059B) styles.

On the basis of the data you submitted, including testing of the functional performance of Tyvek® during medical device sterilization and maintenance of package integrity over time, FDA has determined that the performance of the new Tyvek material is functionally equivalent to the existing Tyvek material. Therefore, it is not necessary, absent a specific request or notice from FDA or a risk analysis finding to the contrary, 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 an upgraded spinning process.

When DuPont communicates this material equivalence determination to medical device manufacturers, please convey the following information about the documentation of their implementation of the new Transition Tyvek® material, including both coated and uncoated Tyvek® styles 1073B and 1059B, in accordance with FDA's device Quality System regulation (21 CFR part 820):

- 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®.

CDRH will also be communicating directly with registered device manufactures in the near future to ensure all manufacturers are aware of this information.

FDA appreciates DuPont's open communication to facilitate a smooth transition.

Sincerely,

Jeffrey Shuren, M.D., J.D.
Director
Center for Device and Radiological Health, FDA