DEPARTMENT OF HEALTH & HUMAN SERVICES

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

OCT 18 2012

Michael H. Scholla, Ph.D.
Global Director, Regulatory and Standards
DuPont Protection Technologies
4417 Lancaster Pike/CRP728-3319
Wilmington, DE 19805

Dear Dr. Scholla:

We have completed our review of the document entitled "*Protocol for Transition of the Medical Device Industry to Tyvek® Manufactured Using an Upgraded Spinning Process*", revised addendum dated August 15, 2012. In this document, DuPont detailed limited studies designed to demonstrate the functional equivalence of Tyvek® non-wovens manufactured under an upgraded flash-spinning process to Tyvek® products manufactured by the present process.

We are in agreement with the study design and testing proposed. Upon successful completion of the proposed tests and demonstration of satisfactory evidence that performance (manufacturability, sterility, seal integrity, etc.) of Tyvek® products from the upgraded process is functionally equivalent to existing Tyvek® products, FDA will then not routinely require Sponsors to amend either their 510(k)s or PMAs that use Tyvek® produced under the new process for their packaging. FDA will require that the Tyvek® manufacturing change be documented in each applicable device record.

DuPont may continue to move forward with the protocol for transitioning Tyvek® production lines 1 & 2, located at the DuPont Spruance plant in Richmond, VA. Please contact FDA when performance and accelerated aging data are available.

Sincerely,

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