



DEPARTMENT OF HEALTH & HUMAN SERVICES

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MAR 1 2011

Food and Drug Administration  
10903 New Hampshire Avenue  
WO62, Suite 3210  
Silver Spring, MD 20993-0002

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 February 22, 2011. 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, package 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.

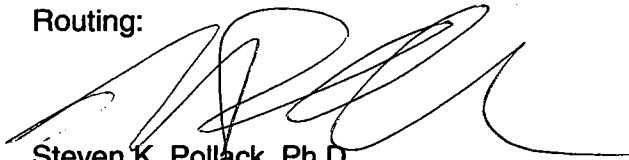
DuPont may at this time move forward with the protocol for transitioning Tyvek® production lines 1 & 2, located at the DuPont Spruance plant in Richmond, VA. Please contact FDA when performance and accelerated aging data are available.

Sincerely,

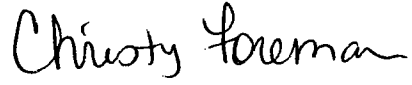
A handwritten signature in black ink, appearing to read "Jeffrey Shuren".

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

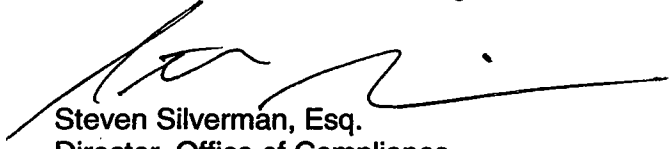
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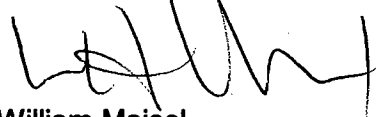
Steven K. Pollack, Ph.D.  
Director, Office of Science and Engineering Laboratories  
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Christy Foreman  
Acting Director, Office of Device Evaluation  
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Steven Silverman, Esq.  
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