



**5-Day Notice (Device/Manufacturing Change) Review Complete**

Cynthia Powell  
G150258/S003

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

The Food and Drug Administration (FDA) has reviewed the 5-Day Notice (Device/Manufacturing Change) to your Investigational Device Exemption (IDE) Application and has determined that you have met the requirements of 21 CFR 812.35(a)(3). No further information is required at this time. This notification is being sent in lieu of a formal written letter. If you have any questions, please contact Paula Caposino at 301-796-6160 or [Paula.Caposino@fda.hhs.gov](mailto:Paula.Caposino@fda.hhs.gov).