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February 28, 2018

Food and Drug Administration
Center for Devices and Radiological Health
IDE Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: IDE G150258 **5-Day Notice 002**

Dear FDA Review Team:

Please find enclosed three copies (1 paper and 2 electronic) of this 5-Day Notice for the above referenced sponsor-investigator IDE. Included in this submission is a summary of the proposed procedural change, an assessment that the change does not have a significant impact on the study design, and an assessment that the change does not affect the safety or welfare of study subjects.

- This is an original IDE submission.
- The device under review for this trial is the following:
  NC NEXUS (North Carolina Newborn Exome Sequencing for Universal Screening) research study and its intended use is to investigate the potential of genome scale next generation sequencing to augment and extend current newborn screening in a diverse pediatric population
- The sponsor of this IDE is Cynthia Powell, MD and her contact information is the following:
  Cynthia M. Powell, MD
  Professor of Pediatrics and Genetics
  Director, Medical Genetics Residency Program
  Division of Pediatric Genetics and Metabolism
  Department of Pediatrics
  University of North Carolina Medical Center
  Chapel Hill, NC 27599-7487
  919-966-4202 (phone)
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- The "device" is not manufactured, thus there is no manufacturer information.

The e-copy is an exact duplicate of the paper copy

Thank you in advance for the FDA's review of this 5-Day Notice. Please contact me if you have any questions.

Sincerely,

Cynthia M. Powell

Cynthia M. Powell, MD