Cynthia M. Powell, MD
Professor of Pediatrics and Genetics; Director, Medical Genetics Residency Program
The University of North Carolina at Chapel Hill
Department of Pediatrics
Chapel Hill, North Carolina 27599-7487

Re: G150258/R005
Trade/Device Name: NC NEXUS (North Carolina Newborn Exome Sequencing for Universal Screening)
Dated: December 16, 2020
Received: December 17, 2020
CMS Category: A

Dear Cynthia Powell:

The Food and Drug Administration (FDA) acknowledges completion of your clinical investigation entitled "NC NEXUS Study" and the submission of the final report to your Investigational Device Exemption (IDE) application. Your submission was amended via email dated January 05, 2021 to reflect the number of individuals approached and enrolled, versus couples, to be consistent with earlier reports.

We wish to remind you that, as part of your responsibilities as the sponsor of this investigation, you are also required to submit a final report to all reviewing institutional review boards (IRBs) and all participating investigators within 6 months after completion of your investigation (i.e., within six months after the last subject enrolled completes follow-up in accordance with the approved investigational plan) (21 CFR 812.150(b)(7)).

FDA now considers this IDE application closed.

If you have any minor clarification questions concerning the contents of the letter, please contact Shirin Marfatia at 301-796-2038 or Shirin.Marfatia@fda.hhs.gov.

Sincerely,

Juliane C. Lessard -S
Date: 2021.01.06 23:49:13 -05'00'

For: Kellie B. Kelm, Ph.D.
Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health