DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 22, 2015

University Of North Carolina at Chapel Hill
Cynthia M. Powell, M.D.
Professor of Pediatrics and Genetics
Department of Pediatrics
CB #7487
Medical School Wing E, Room 117
Chapel Hill, North Carolina 27599-4202

Re: G150258
Trade/Device Name: NC Nexus (North Carolina Newborn Exome Sequencing For Universal Screening)
Dated: November 20, 2015
Received: November 23, 2015
CMS Category: A1 (For procedures to request re-evaluation of the categorization decision, please see the appropriate enclosure)
Annual Report Due: One Year from the Date of This Letter

Dear Dr. Cynthia Powell:

The Food and Drug Administration (FDA) has reviewed your Investigational Device Exemption (IDE) application regarding your research study that is considered a clinical investigation of a significant risk device. FDA has determined you have provided sufficient data to support initiation of a human clinical study; this means that there are no subject protection concerns that preclude initiation of the investigation. Your application is therefore approved, and you may begin your investigation after you have obtained institutional review board (IRB) approval. Your investigation is limited to 1 US institution and 400 US subjects.

We would like to point out that approval of an IDE application does not ensure that the results of this investigation will provide a reasonable assurance of the safety and effectiveness of your device or assure a determination of clearance/approval for your premarket submission.

FDA will waive those requirements regarding submission and prior FDA approval of a supplemental application and receipt of certification of institutional review board (IRB) approval for investigational sites (21 CFR 812.35(b)) provided that the total number of investigational sites does not exceed the limit identified in this letter. As a reminder, you must submit a supplemental IDE application, and receive FDA approval, prior to expanding the investigation beyond the site limit specified in this letter. In addition, you must maintain current records as required by 21 CFR 812.140 and submit reports as required by 21 CFR 812.150. If a reviewing IRB requires any significant changes in the investigational plan or in the informed consent that may increase the risks to subjects or affect the scientific soundness of the study, then this change

must be submitted to FDA for review and approval prior to initiating the study at that investigational site (21 CFR 812.35). Minor changes requested by the IRB may be made without prior FDA approval.

For clarification regarding FDA decisions and recommendations for IDEs, please refer to the FDA guidance "FDA Decisions for Investigational Device Exemption Clinical Investigations: Guidance for Sponsors, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff," available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279107.pdf.

FDA encourages sponsors to collect clinical trial data in accordance with the Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126396.pdf) and to enroll patients that would reflect the demographics of the affected population with regard to age, sex, race and ethnicity. Reference is made to 21 CFR 812.25(c) regarding description of patient population and to 21 CFR 814.15(d)(1) with regard to the need for data, including foreign data, to be applicable to the U.S. population and U.S. medical practice. We recommend that you include a background discussion of prevalence, diagnosis and treatment patterns for the type of disease for which your device is intended. This should include sex- and race-specific prevalence, identification of proportions of women and minorities included in past trials for the target indication, and a discussion of your plan to address any factors identified or suggested, which may explain potential for under-representation of women and minorities, if applicable. We recommend that you include a summary of this information in your protocol and investigator training materials. Consideration should be given to enrollment of investigational sites where recruitment of needed populations for study can be more easily facilitated.

Future correspondence concerning this application should be identified as an IDE supplement referencing the IDE number above, and must be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
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Information to help you understand the function and duties of a sponsor, titled, "Sponsor's Responsibilities for a Significant Risk Device Investigation," is available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm049859.htm. Additionally, information which you should provide to participating investigators, titled, "Investigators' Responsibilities for a Significant Risk Device Investigation," is available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm049864.htm.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. In addition, we strongly encourage you to visit FDA's eSubmitter website at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you have any minor clarification questions concerning the contents of the letter, please contact Sunita Shukla, PhD at 301-796-6406 or Sunita.Shukla@fda.hhs.gov.

Sincerely yours,

Katherine Serrano -S

For:

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
Procedures to Request Re-Evaluation of CMS Reimbursement Categorization Determination

PROCEDURES TO REQUEST RE-EVALUATION OF CMS REIMBURSEMENT CATEGORIZATION DETERMINATION

You may submit a request for re-evaluation of the CMS reimbursement categorization determination at anytime, i.e., there is no time limit in which you need to make this request.

In order to request a re-evaluation regarding FDA's determination of CMS reimbursement category, you are required to file an IDE supplement with FDA in which you identify the reason(s) you believe the categorization is incorrect and provide supporting documentation. The cover letter to the IDE supplement should clearly identify it as a request for re-evaluation of CMS reimbursement categorization determination, reference the IDE number, and must be submitted in duplicate to:

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