DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

02/27/2014

CRISTINA KAPUSTIJ
INSTITUTE FOR HUMAN GENETICS
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
513 PARNASSUS AVENUE, 901D
SAN FRANCISCO, CA 94143
United States

Dear CRISTINA KAPUSTIJ:

The Food and Drug Administration (FDA) acknowledges receipt of your submission. FDA considers this information to be a Q-Submission (Q-Sub). Q-subs include Pre-submissions, informational meeting requests, submission issue meeting requests, study risk determinations, and requests for Determination and Agreement Meetings. It has been assigned the following document control number:

Q-Submission Number: Q140229 Received: 02/26/2014 Dated: 02/14/2014
Device: ILLUMINA HISEQ

Your Q-Sub will receive the same confidentiality as provided for IDE applications under 21CFR 812.38 of the IDE regulation (21 CFR PART 812). FDA will not disclose the existence of your submission, unless its existence has previously been publicly disclosed or acknowledged, until FDA approves a marketing application for the device subject to this submission.

It is our goal to provide feedback on your submission within 90 days, whether in the form of a meeting, teleconference, letter, or email. If you have requested a meeting, we will contact you in approximately 3 weeks to schedule the meeting.

FDA's Center for Devices and Radiological Health (CDRH) is committed to educating industry on relevant premarket and postmarket policies and regulations for medical devices. CDRH's latest innovative educational tool is CDRH Learn, which consists of a series of training modules that are intended to provide an information resource that is comprehensive, interactive, and easily accessible. CDRH Learn can be accessed at: <http://www.fda.gov/Training/CDRHLearn/default.htm>

Any future correspondence regarding this submission should be identified with your Q-Sub number and be submitted to the above address.

Sincerely,

Sheila Brown
Nurse Consultant
IDE Program
Office of Device Evaluation
Center for Devices and Radiological Health