



**Acknowledgment Letter**

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

02/27/2015

DR. ROBERT NUSSBAUM  
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
513 PARNASSUS AVENUE, 901D  
SAN FRANCISCO, CA 94143  
United States

Dear DR. ROBERT NUSSBAUM:

The Food and Drug Administration (FDA) acknowledges receipt of your submission. FDA considers this information to be a Q-Submission (Q-Sub). Q-submissions 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/S001  
Received: 02/27/2015  
Dated: 02/25/2015  
Applicant: UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
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