

**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

06/04/2015

Adam Himes, M.S.  
Medtronic plc, Cardiac Rhythm and Heart Failure  
Medical Device Innovation Consortium  
1550 Utica Avenue South, Suite 740  
St. Louis Park, MN 55416  
United States

Dear Adam Himes, M.S.:

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: Q150804  
Received: 06/04/2015  
Dated: 05/27/2015  
Applicant: Medical Device Innovation Consortium  
Device: MDIC mock submission for clinical trial argued with virtual patient data

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,

Soma Kalb, Ph.D.  
Director, IDE Program  
Office of Device Evaluation  
Center for Devices and Radiological Health