May 27, 2015

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Pre-Sub Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Informational meeting to discuss MDIC mock submission for clinical trial augmented with virtual patient data

To Whom It May Concern:

This submission is to request an informational meeting with FDA regarding the Medical Device Innovation Consortium (MDIC) project to create a mock IDE submission focusing on using virtual patient data to augment a clinical trial. This meeting has been discussed with Mitchell Shein and Erin Cutts in Boston, MA on May 14, 2015.

Once the primary reviewer has been identified, MDIC will work with FDA to agree upon a time and date for this meeting. We are requesting a meeting at FDA, approximately 90 minutes.

Sponsor Information:

Name: Medical Device Innovation Consortium
1550 Utica Avenue South, Suite 740
St. Louis Park, MN 55416
952-314-1255
mdic.org

Primary Contact: Adam Himes, M.S.
Senior Principal Engineer
Medtronic plc, Cardiac Rhythm and Heart Failure
tel: 763-526-9414 cell: 612-309-9971
fax: 763-526-9414
E-Mail: adam.k.himes@medtronic.com

Two copies of this meeting request and supporting documents are being submitted: one paper copy and one CD-ROM. The information being provided via CD-ROM is an exact copy of the paper copy. The supporting documents include a short paper describing the project and presentation slides giving a visual overview of the approach.

If you have any questions, or if further information is required, please contact the undersigned.

Regards,

Adam Himes, on behalf of the MDIC working group on clinical trials informed by bench and simulation