DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 21, 2018

Carol Grutkoski
University of Minnesota
McNamara Alumni Center
200 Oak Street SE, Suite 280
Minneapolis, MN 55455

Re: MDDT026
MDDT Name: Minnesota Living with Heart Failure Questionnaire
MDDT Type: Clinical Outcome Assessment
Dated: July 27, 2016
Received: August 1, 2016

Dear Carol Grutkoski:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of Medical Device Development Tool (MDDT) Qualification Package for the Minnesota Living with Heart Failure Questionnaire (MLHFQ). We are pleased to inform you that the MDDT is qualified for the following context of use (COU):

> The paper self-administered version of the MLHFQ can be used to determine whether a device treatment is effective for improving patients' quality of life by reducing the adverse impact of heart failure. The instrument can be used as a secondary endpoint in feasibility and pivotal studies of outpatients with symptomatic (NYHA class II and III) heart failure. The 21-item instrument is completed by patients after they have been properly instructed by study staff. Study staff should be properly trained to instruct the patient and if needed, administer the questionnaire, according to pre-set administration instructions. The MLHFQ instrument may be used by medical device companies and sponsor-investigators in controlled clinical trials designed to test superiority or non-inferiority of medical devices in support of regulatory submissions.

This qualification determination does not constitute marketing clearance or approval of this product as a medical device, and does not affect a previous clearance or approval of a device.

Once an MDDT is qualified for a specific COU, CDRH intends to accept its use by any medical device sponsor for that COU. When used within the above COU, the results of an assessment that uses this MDDT can be relied upon in medical device evaluation in a regulatory submission without the need to reconfirm with CDRH the suitability and

utility of the MDDT. CDRH maintains the responsibility for evaluating regulatory submissions using information obtained from a qualified MDDT.

MDDT qualification does not obviate the need for a medical device sponsor to meet existing regulatory requirements, nor does it alter the benefit-risk threshold for regulatory decision-making related to a medical device; rather, it can facilitate the development and regulatory evaluation of a medical device by providing a more efficient and predictable means for collecting the necessary information to make regulatory assessments.

The use of an MDDT in a medical device clinical study does not change the IDE requirements for a given investigation.

CDRH will notify the public of its decision to qualify your MDDT. You have provided consent for FDA to make public certain information regarding this qualified MDDT.

Nothing about the MDDT program is intended to place limitations or requirements on MDDT licensing or fees, or the degree of access to intellectual property associated with an MDDT that a tool developer may give to a device sponsor.

You may request that CDRH incrementally expand or otherwise modify the qualified COU in response to new data or changing science by submitting a new qualification package. CDRH also intends to reconsider qualification decisions as appropriate. For example, if the bases upon which an MDDT was qualified have changed, CDRH may re-evaluate the qualification decision.

If you have any questions concerning this qualification decision letter, please contact Arielle Drummond, PhD at 240-402-6533 or Arielle.Drummond@fda.hhs.gov.

Sincerely yours,

Randall G. Brockman -S

Randall Brockman, MD
Clinical Deputy Director
Office of Device Evaluation
Center for Devices and Radiological Health