BHR Limited
Katharine Barnard-Kelly, Ph.D.,
Health Psychologist & Managing Director
42 Kilmiston Drive
Fareham, Hampshire, PO16 8EG
UNITED KINGDOM

Re: Q-Submission Number: Q191073
MDDT Name: Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations (INSPIRE) Questionnaires
MDDT Type: Clinical Outcome Assessment
Dated: November 20, 2019
Received: November 22, 2019

Dear Katharine Barnard-Kelly:

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 INSPIRE Questionnaires. We are pleased to inform you that the MDDT is qualified for the following context of use (COU):

> The self-administered INSPIRE (INsulin Dosing Systems: Perceptions, Ideas, Reflections and Expectations) questionnaires have been developed to determine the impact of AID systems on psychosocial functioning and quality of life in youth with T1D (8-17 years of age) and adults with T1D, as well as parents/caregivers of youth with T1D, and partners of adults with T1D. The INSPIRE questionnaires can be used by medical device companies and sponsors or investigators of clinical studies to determine the impact of automated insulin dosing (AID) systems on psychosocial functioning and quality of life in individuals with T1D and to support the safety and effectiveness of these systems.
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> The INSPIRE questionnaires have been developed to determine the psychosocial impact of AID systems in a range of relevant factors specific to youth with T1D (8-17 years of age) and adults with T1D, as well as parents/caregivers of youth with T1D, and partners of adults with T1D.
>
> The baseline and/or post-intervention versions of the INSPIRE questionnaires may be used as secondary or additional endpoints in a clinical study to evaluate subjects' perceptions of the impact of AID systems on their psychosocial functioning and quality of life. In addition, the baseline and post-intervention questionnaires can be administered longitudinally to characterize changes in these factors from baseline. Including user perspective information may be helpful to understand the benefits and risks of AID systems. Sponsors should engage with FDA to determine the applicability of the INSPIRE questionnaires to their clinical study.

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.

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 Susan Walker at 301-796-6204 or susan.walker@fda.hhs.gov

Sincerely yours,

Timothy Stenzel, M.D., Ph.D.
Director
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Heal