May 25, 2023

University of Michigan
William Meurer
Associate Professor Emergency Medicine and Neurology
Taubman Center B1-354
1500 E. Medical Center Drive
Ann Arbor, Michigan 48109-5301

Re: G210126/S005
Trade/Device Name: Pediatric Influence of Cooling duration on Efficacy in Cardiac Arrest Patients
Dated: May 9, 2023
Received: May 10, 2023
CMS Category: B
Annual Report Due: May 26, 2023

Dear William Meurer:

The Food and Drug Administration (FDA) has reviewed the supplement to your Investigational Device Exemption (IDE) application to expand your pivotal study (P-ICECAP) for a significant risk device proposing the addition of 10 institutions. FDA has determined you have provided sufficient data to support expansion of your human clinical study; this means that there are no subject protection concerns that preclude expansion of the investigation. Your supplement is therefore approved, and you may expand your study. Your investigation is limited to 50 US institutions and 500 US subjects.

Your IDE application has been approved as a staged study. You may request approval to expand enrollment in your study when you have submitted the following:

1. A detailed interim report, formulated by the unblinded DSMB statistician, submitted to FDA and the DSMB after 400 subjects enrolled and treated (with at least 30 day follow up data). The purpose of this report is to identify otherwise unrecognized ongoing safety issues appropriate for informing stopping decisions as well as for monitoring the fidelity of designed enrollment and randomization patterns.

2. Detailed minutes for the DSMB meeting (open and closed sessions) following this interim report.

3. The interim report request in item 1 above should inclue a comprehensive clinical report (including at a minimum, adverse event information and appropriately supportive patient line-item data (e.g., temperature and outcomes data for each subject) on the first 400 subjects enrolled and treated (with all follow-up information available). In addition, this report should include a detailed analysis of

aggregate safety and effectiveness results for the pooled 400 patient as well as further stratification by TTM device, by cooling duration arm, and by TTM plus cooling duration arm.

These staged conditions have been implemented so that FDA can continue to appropriately monitor study procedures and patient safety in this trial of a vulnerable pediatric population. .

You must also obtain institutional review board (IRB) approval before implementing this change in your investigation as required by 21 CFR 812.35(a) because FDA believes this change affects the rights, safety, or welfare of subjects.

FDA will waive those requirements regarding prior approval of a supplemental IDE application for investigational sites (21 CFR 812.35(b)) provided that the total number of investigational sites does not exceed the limit identified in this letter. Under this waiver, the study may be initiated at new sites, up to the approved limit, and updated information required by 21 CFR 812.20(b) on participating investigators and associated Institutional Review Boards (IRBs) and the IRB approval documentation may be submitted all at once in your IDE annual progress report. You must, however, submit a supplemental IDE application, and receive FDA approval, prior to expanding the investigation beyond the site limit specified in this letter. In addition, you must maintain current records as required by 21 CFR 812.140 and submit reports as required by 21 CFR 812.150. If a reviewing IRB requires any significant changes in the investigational plan or in the informed consent that may increase the risks to subjects or affect the scientific soundness of the study, then this change must be submitted to FDA for review and approval prior to initiating the study at that investigational site (21 CFR 812.35). Minor changes requested by the IRB may be made without prior FDA approval. FDA also will waive the requirement for 6-month current investigator lists (21 CFR 812.150(b)(4)) provided that current investigator information is submitted every 12 months as part of the IDE annual progress report.

In order for your study to serve as the primary clinical support for a future marketing approval or clearance, FDA has provided additional study design considerations as an attachment to this letter. These recommendations do not relate to the safety, rights or welfare of study subjects and they do not need to be addressed in order for you to conduct your study. You are reminded that prior to implementing any significant modifications to the approved investigational protocol you must obtain FDA approval, and, if appropriate, IRB approval for the changes.

Future correspondence concerning this application should be identified as an IDE supplement referencing the IDE number above, and must be submitted following eCopy guidelines to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
IDE Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a single paper copy of your signed

cover letter. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's eCopy program, including the technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at https://www.fda.gov/media/83522/download. In addition, we strongly encourage you to visit FDA's eSubmitter website at https://www.fda.gov/industry/fda-esubmitter/cdrh-esubmitter-program in order to develop an eCopy in accordance with the technical standards prior to sending it to FDA.

If you have any minor clarification questions concerning the contents of the letter, please contact Catherine P. Wentz at 301-796-6339 or Catherine.Wentz@fda.hhs.gov.

Sincerely,

Jaime Raben -S

Jaime Raben, PhD
Acting Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Additional Recommendations and Considerations