



March 26, 2025

University of Michigan
William Meurer
Associate Professor Emergency Medicine and Neurology
Taubman Center B1-354F
1500 E. Medical Center Drive
Ann Arbor, Michigan 48130

Re: G210126/S006

Trade/Device Name: Pediatric Influence of Cooling duration on Efficacy in Cardiac Arrest Patients

Dated: February 24, 2025

Received: February 24, 2025

CMS Category: B

Annual Report Due: May 26, 2025

Dear William Meurer:

The Food and Drug Administration (FDA) has reviewed the supplement to your Investigational Device Exemption (IDE) application regarding your pivotal study (P-ICECAP) for a significant risk device proposing to include OUS sites as well as the possibility of enrolling these subjects under a “deferred consent” process in accordance with the procedures and legislation of the jurisdiction. FDA has determined you have provided sufficient data to support continuation of your human clinical study; this means that there are no subject protection concerns that preclude continuation of the investigation. Your supplement is therefore approved, and you may implement that change in 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 include 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.

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,

Rachel E. Neubrandner -S

Rachel Neubrandner, PhD

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