August 5, 2026

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

Re: G210126/S007
Trade/Device Name: Pediatric Influence of Cooling duration on Efficacy in Cardiac Arrest Patients
Dated: July 6, 2026
Received: July 6, 2026
CMS Category: B
Annual Report Due: May 26, 2027

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 400 patients. 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 900 US 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.

FDA acknowledges that your investigation will include foreign sites. FDA does not have jurisdiction over foreign sites; therefore, you may proceed at those foreign sites at your discretion. We encourage you however, to follow a uniform protocol at the domestic and the foreign investigational sites. Please note that FDA will accept data from studies conducted outside the United States if you demonstrate that the data are adequate to support a premarket submission (e.g., an IDE, or a marketing application or submission). Section 812.28 of the IDE regulation provides the requirements for studies conducted outside the United States that began on or after February 21, 2019, and are submitted in support of a premarket submission. For additional information please refer to the FDA Guidance "Acceptance of Clinical Data to Support Medical Device Applications and Submissions", available at: https://www.fda.gov/media/111346/download.

For studies conducted outside the United States that began before February 21, 2019, and are submitted in support of a premarket approval (PMA) application, FDA will accept the data if the data are valid and the investigators have conducted the studies in accordance with the "Declaration of Helsinki" or the laws and regulations of the country in which the study is conducted, whichever afford greater protection to the human subjects. If the country's standards are used, you must state in detail any differences between the country's standards and the "Declaration of Helsinki" and explain why the country's standards afford greater protection to the human subjects.

Furthermore, to export a device that is not in commercial distribution in the U.S. you must comply with Section 802 of the Federal Food, Drug and Cosmetic Act (the act). Detailed information regarding export requirements for investigational devices is available at: https://www.fda.gov/medical-devices/exporting-medical-devices/exporting-unapproved-devices.

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 can be submitted as a complete eCopy or eSTAR file, electronically through the CDRH portal. For more information about the eCopy program, please visit https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-medical-device-submissions. For more information about the eSTAR program, please visit https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

For CMS-covered IDE studies, you should make CMS aware of any FDA-approved IDE protocol changes by sending the updated FDA approval letter and the revised protocol with all changes identified to clinicalstudynotification@cms.hhs.gov.

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 Neubrander, 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