December 20, 2024

Conformal Medical, Inc.
Steve Chartier
Vice President, Regulatory and Quality
15 Trafalgar Square, Suite 101
Nashua, New Hampshire 03063

Re: G180189/S041
Trade/Device Name: Conformal Left Atrial Appendage Closure (LAAC) System
Dated: December 11, 2024
Received: December 11, 2024
CMS Category: B
Annual Report Due: September 7, 2025

Dear Steve Chartier:

The Food and Drug Administration (FDA) has reviewed the supplement to your Investigational Device Exemption (IDE) application regarding your pivotal study for a significant risk device requesting to resume your study and to modify both your clinical investigational protocol and informed consent form, with revisions to these protocols provided interactively on December 17, 2024. 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 100 US institutions and 1900 US subjects (300 Roll-In and 1600 Randomized).

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.

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.

We note that you have designed this protocol to collect safety and effectiveness data to support submission of a future PMA application. Regarding the statistics to be presented in the PMA, we expect analysis of the primary dataset to contain one line per unit (e.g., person, sample, observation) with clinical outcomes and baseline covariates. You should also provide the statistical program code which produces the above analyses and which clearly documents variable definitions and coding schemes, as well as the data, in an electronic format (e.g., SAS, S-Plus or R, Excel, ASCII).

If approved, it is likely that a post-approval study (PAS) may be requested as a Condition of Approval (CoA). As the original IDE cohort can sometimes be used to gather long-term safety and effectiveness data after market approval, we suggest you consider obtaining patient informed consent and IRB approval at the initiation of the study so that enrolled subjects will be followed for a period of at least 5 years. FDA believes this may reduce patient loss to follow-up during the marketing application review process and keep many subjects available to participate in such a PAS if ordered. In addition, please note that other clinical studies apart from continued follow-up of IDE subjects, including prospective studies which enroll new patients, may also be required as CoA should a future marketing application be approved.

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 Emily Olszewski at +1(301)796-2173 or Emily.Olszewski@fda.hhs.gov.

Sincerely,

Rachel E. Neubrander -S

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

ADDITIONAL RECOMMENDATIONS AND CONSIDERATIONS

The recommendations and/or considerations below 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.

Study Design Considerations

FDA believes that you should give serious consideration to the major study design considerations listed in our G180189/S028 letter dated September 21, 2023, our G180189/S029 letter dated October 13, 2023, and our G180189/S036 letter dated March 7, 2024, which FDA consider important for the support of a future submission.

If you intend to propose changes to your study to address these Study Design Considerations you should submit an IDE supplement.

Future Considerations

You should also give serious consideration to the future considerations listed in our G180189/S016 letter dated November 3, 2021, which FDA considers important for the support of a future submission.

The Future Considerations listed above are intended to assist in your plans for a future marketing application only. No response is necessary under this IDE, unless you wish to modify your device or study to address these concerns, in which case approval of an IDE supplement may be needed.

If you would like FDA's feedback on your plans for addressing any additional recommendations and considerations, please submit a Pre-Submission. Your submission should reference this IDE, identify the specific Study Design Considerations and/or Future Considerations you wish to discuss, and indicate your preferred feedback mechanism (i.e., email, meeting or teleconference). Additional information regarding Pre-Submissions is available in the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.