October 24, 2023

Openwater
% Prabhu Raghavan
Regulatory Consultant
MDQR, LLC
1790 Montemar Way
San Jose, California 95125

Re: Q211873/S001
Trade/Device Name: Openwater LVO Stroke Alert
Received: August 15, 2023

Dear Prabhu Raghavan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received the above submission requesting designation as a Breakthrough Device. We regret to inform you that your device and the proposed indication do not meet the criteria for designation as a Breakthrough Device and your request has been denied. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at https://www.fda.gov/media/108135/download.

Designation as a Breakthrough Device is not granted for the following reasons:

1. To meet Breakthrough Device designation criterion #1 as defined by Section 515B(b)(1) of the Federal Food, Drug, and Cosmetic (FD&C) Act [21 U.S.C. 360e-3(b)(1)], you need to demonstrate a reasonable expectation that the proposed device could provide for more effective diagnosis or treatment of the target irreversibly debilitating or life-threatening disease or condition compared to current available methods. Based on the information provided during the review of the Q211873/S001 submission, including the responses to the deficiencies in the September 20, 2023, request for additional information (AIRQ) letter, the preliminary evidence of the performance of the Openwater LVO [Large Vessel Occlusion] Stroke Alert does not demonstrate a reasonable expectation that a functioning device could more effectively treat or diagnose the type and location of an occlusion in suspected stroke patients or patients presenting with stroke mimics (clinical success) compared to available methods in the intended pre-hospital setting that is required per criterion #1 in Section 515B(b)(1) of the FD&C Act [21 U.S.C. 360e-3(b)(1)] for your device to be designated as a Breakthrough Device. Section 3.1.1, "Feasibility Assessment 1 – Cross-Validation," in the original Q211873/S001 submission stated that the results of your feasibility study indicate the "*Openwater LVO Stroke Alert's algorithm showed a sensitivity of 81%, a specificity of 80% … The balance of sensitivity and specificity well above current hospital stroke scores is encouraging and speaks to the potential of the proposed device in assessing patients in a prehospital setting*". The study assessed the device's performance in a controlled hospital setting in patients with anterior LVO, non-LVO stroke, and stroke mimics. However, this does not demonstrate that the device could perform

effectively and reliably in the intended pre-hospital setting because of the variety of factors that could impact the device's performance in this setting, including patient movement, the experience of the emergency medical technicians (EMTs), ambulance motion, lighting conditions, the variety of stroke mimics encountered in the pre-hospital setting (including intracranial bleeds, tumors that may mimic acute ischemic stroke, posterior circulation LVO), and others. To support the determination that your device has a reasonable expectation to provide a more effective diagnosis of LVO stroke compared against emergency medical service (EMS) stroke assessments in the intended pre-hospital setting to meet criterion #1 in Section 515B(b)(1) of the FD&C Act [21 U.S.C. 360e-3(b)(1)], we request that you provide clinical performance data demonstrating that the Openwater LVO Stroke Alert can accurately detect and distinguish between LVO stroke and other occlusions or stroke mimics in suspected stroke patients by EMTs in the intended pre-hospital setting to quantify inaccuracies and device failure due to considerations such as ambulance movement during device use. These resulting device outputs should be compared against ground truth diagnostic imaging, such as computed tomography (CT) or magnetic resonance imaging (MRI).

Even though we have determined that your device does not qualify for the Breakthrough Device designation, you may use the Pre-Submission review process, as described in the Pre-Submission guidance available at https://www.fda.gov/media/114034/download, to request feedback from FDA. This new submission should be provided as an eCopy, it should include the FDA reference number for this Pre-Submission, and should be submitted to the following address:

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

If you disagree with the decision identified in this letter, please note, the most effective means for resolving disputes is through discussion with the CDRH staff who reviewed your submission. If these approaches fail to resolve the disagreement, you may request supervisory review under 21 CFR 10.75. Most actions taken by CDRH can be revisited under this Section, which is a general-purpose mechanism to request supervisory review of a decision made by CDRH staff. The general expectation is that there will be an orderly progression of interaction with CDRH review staff, followed by outreach to relevant members of Management and then engagement with the CDRH Ombudsman, prior to filing an appeal under 10.75. A request for supervisory review should be directed at the next organizational level above the level at which the action was taken.

If you have any questions, please contact Julia Donlon at Julia.Donlon@fda.hhs.gov.

Sincerely,

Xiaolin Zheng -S

Xiaolin Zheng, Ph.D., M.S.
Director
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