September 20, 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 have the following questions with regards to your request.

The items described below identify areas where deficiencies exist with your Request for Designation as a Breakthrough Device, including an explanation of why the device not meet the criteria outlined, and what additional information is needed to address .

1. The proposed indications for use (IFU) of the Openwater LVO Stroke Alert in the Breakthrough Device request (Q211873/S001) is: "*Openwater LVO Stroke Alert is indicated for use as an early notification system to identify patients suspected of large vessel occlusion (LVO) in the anterior circulation. This software as a medical device (SaMD) utilizes data from Openwater Headset in adult patients. Openwater LVO Stroke Alert is intended to be used in hospitals, clinics, and in pre-hospital settings*." The Breakthrough Device designation requires that you must provide scientific evidence to meet 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)] to generate a reasonable expectation that the subject device could provide for more effective diagnosis or treatment of the target condition compared to current usual care methods and thus demonstrate clinical success. The feasibility study data provided in the Q211873/S001 submission does not demonstrate that the Openwater LVO Stroke Alert has both better sensitivity and specificity to distinguish LVO stroke compared to stroke caused by small or medium vessel occlusions, stroke mimics, or intracranial hemorrhage when used in the pre-hospital setting by emergency medical services (EMS) compared to the current clinical assessment tools. For example, the specificity of the Openwater LVO Stroke Alert is comparable or slightly less than the RACE (Rapid Arterial Occlusion Evaluation) and LAMS (Los Angeles Motor Scale) assessments performed in the pre-hospital setting, while the sensitivity is higher. Both sensitivity and specificity are important outcomes to show that the subject device is a better diagnostic assessment tool compared to the current assessments used in the pre-hospital setting because sensitivity demonstrates that the device can accurately identify the true LVO strokes,

whereas specificity is important for the device to accurately distinguish LVO strokes from other clinical diseases or conditions, such as stroke mimics, intracranial hemorrhage, or small and medium vessel occlusion strokes. Furthermore, diagnostic imaging using computed tomography (CT) or a magnetic resonance (MR) scanner is used for the diagnosis of stroke upon presentation to the clinic or hospital and you have not provided any scientific evidence in the Q211873/S001 submission for the use of your device in the hospital and clinical settings and that it offers better diagnosis of stroke than CT or MR imaging. The feasibility study data shows that the use of the Openwater LVO Stroke Alert with the Openwater Headset has 81% sensitivity and 80% specificity to diagnose LVO stroke compared to CT or MR imaging modalities. These results indicate that the subject device does not have the same or better sensitivity and specificity of diagnosing the site of vessel occlusion compared to the current imaging modalities for the proposed indicated use in the clinic and hospital settings to satisfy Breakthrough Device criterion #1 as defined by Section 515B(b)(1) of the Federal FD&C Act [21 U.S.C. 360e-3(b)(1)].

The current available methods in the pre-hospital phase include stroke ambulances, telemedicine, trained emergency medical technicians (EMTs), and protocols that take into account current traffic delays, hospital capability to treat rapidly, stroke onset time, and other factors. In some areas, there are even attempts to transport interventionists to the stroke patient. There would have to be evidence that the use of the Openwater LVO Stroke Alert to triage patients to a more remote hospital for endovascular therapy could result in increased benefit and show that patients who could have been treated earlier with thrombolytic therapy did not fare worse when compared to outcomes of patients transported according to the current methodology to make triage decisions. To be more effective than current available diagnosis of stroke occlusion location in the clinic and hospital and other settings per your proposed IFU and satisfy Breakthrough Device criterion #1 as defined by Section 515B(b)(1) of the Federal FD&C Act [21 U.S.C. 360e-3(b)(1)], we request that you provide clinical performance data that demonstrates more accurate diagnosis of stroke occlusion location for all types of stroke or conditions that mimic stroke using the Openwater LVO Stroke Alert compared to current methods as described above.

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.

This is to advise you that an amendment to this Q-submission (Q-Sub) addressing the above requested information must be submitted within 15 days from the date of this request in order to be considered in our decision process. This submission should be provided as an eCopy, it should include the FDA reference number for this Q-Sub, 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 have any questions, please contact Julia Donlon at Julia.Donlon@fda.hhs.gov.

Sincerely,

Xiaolin Zheng -S

Xiaolin Zheng, Ph.D., M.S.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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