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July 27, 2021

Circulatory System Devices Panel
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue, Bldg. 66, Rm. 5214
Silver Spring, MD 20993-0002

Dear Dr. Asefa, FDA Staff, and Members of the Circulatory System Devices Panel:

I am submitting this letter in advance of the August 3, 2021, meeting of FDA's Circulatory System Devices Panel. The purpose of that meeting is to discuss the TriGUARD 3 Cerebral Embolic Protection Device, which is designed to minimize the risk of cerebral damage by deflecting embolic debris away from the cerebral circulation during trans-catheter aortic valve replacement.

I am a Cardiologist in the Texas Medical Center where I am affiliated with UTHealth McGovern Medical School/Memorial Hermann Hospital. Additionally, I serve as Director of Structural Heart and am Associate Professor of Medicine at University of Texas Health Science Center at Houston. My practice focus is Interventional Cardiology. In particular, my clinical focus is complex percutaneous coronary interventions, and transcatheter therapies for structural heart disease. Our program offers transcatheter treatments for the majority of valvular abnormalities.

I was an investigator for REFLECT II Clinical trial, and was on the physician review committee for the same trial. Currently, I do not have any conflicts of interest with Keystone Heart Inc.

Based on the results of the REFLECT data, I support approving this device as it provides 3 vessel complete coveregare for the cerebral circulation during transcatheter aortic valve replacmenet (TAVR), as opposed to the currently available cerebral embolic protection device – Sentinel. The subgroup analysis of REFLECT trial did suggest that the patients who achieved 3 vessel coverage with Triguard device during TAVR experienced less strokes than the control group. Additionally, the device is deployed from femoral artery access site, without need for an additional access during TAVR. The device is easy to use and deploy. It is always good to have a device that can be used for embolic protection during TAVR without adequate radial access, or tortuous neck arteries.

I look forward to hearing this panel's assessment of all the efficacy and safety data from this trial. As an operator with at least 40 cases of experience, I believe the data show the device deflects embolic debris away from the cerebral circulation and does so safely. I think the TriGUARD device should be added to the options available to patients and their clinicians.

Sincerely,

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