

Via email: Aden Asefa at aden.asefa@fda.hhs.gov

July 27, 2021

Members of the 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

RE: August 3, 2021, Circulatory System Devices Panel meeting on the TriGuard 3 cerebral protection device

Dear Members of FDA's Circulatory System Devices Panel:

My name is Anders Jonsson and I work at Akademiska Hospital in Uppsala, Sweden. I have been involved in TAVI since 2009 and have also worked as a proctor for many years and supported the start up of many TAVI programs around the world.

I want to share my experience of the TriGuard 3 cerebral protection device.

At Akademiska Hospital we decided to try and evaluate the latest version of Keystone Heart's TriGuard 3 this autumn 2020 and had a budget for eight devices. Some of the operators in our center, including myself, have previously used a different cerebral protection device but since TAVI operators are not generally trained in carotid interventions, the option of cerebral deflection devices felt like an attractive alternative.

I preformed five of the procedures and, after that, I supported one of our junior operators, who performed the last three.

Our general impression of the device was that it was surprisingly user friendly and easy to incorporate into the TAVI procedure. It did not require an additional access site and could in all of our cases be positioned and stabilized in the aortic arch to cover the takeoff of all three cerebral vessels without unnecessary manipulations. The TAVI procedure could be carried out in all patients without any intraprocedural complications and with good results.

All patients were discharged from the hospital. There were no complications in any of our patients, neither related to the TAVI procedure nor from the usage of the TriGuard 3 device.

I hope this summary of my hospital's real-world experience and results are helpful in your review of the device.

Sincerely,

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