January 7, 2021

Boston Scientific Corp.
Balaka Das
Fellow, Regulatory Affairs
Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, California 91355

Re: P150031/S028
Trade/Device Name: Vercise PC and Vercise Gevia Deep Brain Stimulation (DBS) Systems

Dear Balaka Das:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its review of your premarket approval application (PMA) Supplement and issued an approval order on December 29, 2020. We inadvertently made an error in the wording of your indications for use statement. The correct wording of your expanded indications is for use in bilateral stimulation of the globus pallidus internus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication. These devices are indicated for the are indicated for use in the following:

- Bilateral stimulation of the globus pallidus internus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive PD that are not adequately controlled with medication.

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa responsive PD that are not adequately controlled with medication.

We hope that this error has not inconvenienced you. If you have any questions about this corrective action, please contact Kristen Bowsher, Ph.D. at 301-796-6448 or Kristen.Bowsher@fda.hhs.gov.

Sincerely,

Vivek J. Pinto -S

Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health