U.S. FOOD & DRUG ADMINISTRATION

September 10, 2021

Michael T. Abrams, M.P.H., Ph.D.
Health Researcher
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Dear Drs. Abrams and Carome:

Thank you for the August 17, 2021 letter to Jeffrey Shuren, M.D., J.D., William Maisel, M.D., and Bram Zuckerman, M.D. at the FDA's Center for Devices and Radiological Health (CDRH) regarding the premarket notification submission (510(k)) for the TriGUARD 3 Cerebral Embolic Protection Device (TriGUARD 3).

We appreciate your interest on the August 3, 2021 meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee and your thoughtful review of the data presented during the meeting.

The FDA may seek the advice of its Advisory Committees for various reasons. These committees are comprised of independent experts on clinical and scientific matters. Meetings of the Advisory Committees provide an important open public forum for general matters or specific files to be discussed before the Agency. Although advisory committees provide recommendations to the FDA, the FDA makes the final decisions.

The integrity of the 510(k) program, as a means to assure the substantial equivalence of class II medical devices, is a top priority for the FDA. The legal standard for FDA's 510(k) decisions and the risk-based system for classifying medical devices into class I, II or III is described in detail in the guidance, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (510(k)). In addition, in recent years, the FDA has taken important steps to modernize our approach to 510(k) reviews. These steps are described in the report, FDA Has

Taken Steps to Strengthen The 510(k) Program.

We value the input from all stakeholders and appreciate the time you have taken to write to us. We hope this information is helpful.

Sincerely,

William H. Maisel -S

William H. Maisel, M.D., M.P.H.
Director
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