DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building 66, Room 2621
Silver Spring, MD 20993

April 15, 2014

Document Number: CPT1400358/CPT1400359
AIMS2014-2854

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

Dear Concerned Party:

This is in response to your correspondence, dated April 3, 2014, in which you allege that Stryker Neurovascular and Boston Scientific have published false and misleading information regarding the Wingspan Stent System on their websites.

Thank you for providing this information to the Food and Drug Administration (FDA). Information from regulated industry is often very helpful to us in identifying problems with marketed products and possible violations of the laws that we enforce. We take such reports seriously, and we will evaluate this matter to determine what follow-up action is appropriate. The type and extent of any follow-up is dependent upon the nature of the problem, the possible impact on the public health, and the availability of our resources.

While FDA does not provide information on ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request, once an investigation is closed. Requests for this information can be submitted via the agency online FOIA submission address at http://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm
or in writing to the following address:

Food and Drug Administration
Freedom of Information Staff
ELEM 1029
12420 Parklawn Drive
Rockville, Maryland 20857

If you have any questions regarding this letter, please contact me at 301-796-6117 and reference the above document number.

Sincerely yours,

Donna Engleman, BSN., MS.
Chief, Allegation of Regulatory Misconduct Branch
Center for Devices and
Radiological Health