QUINTESSENTIAL
CAPITAL MANAGEMENT

December 8, 2020

Attention: Allegations of Regulatory Misconduct Team
Office of Regulatory Programs
Center for Devices and Radiological Health
Food and Drug Administration
WO Bldg. 66 RM 1523
10903 New Hampshire Ave
Silver Spring, MD 20993

Via Email

CDRHDeviceAllegations@fda.hhs.gov

Dear FDA,

We write with a formal allegation of regulatory misconduct and request that FDA, initiate the appropriate internal investigations to confirm, assess and respond to the information provided here.

- Name of the company for investigation: Penumbra, Inc.
- Address and telephone number of the company: 1321 Harbor Bay Parkway, Alameda, CA 94502 · (510) 995-2461 (https://www.penumbrainc.com/)
- Name of the device and model: Jet7 series

Regulatory Misconduct Identified and Hereby Reported:

- Significant device malfunctions and related deaths; indicating the device does not meet device design specifications;
    - Evidence Submitted:

  - Thirty Party Assessment: NDA Partners LLC, Quintessential Capital Management "Penumbra Jet7 Flex Assessment"[1];
    - "the Jet7 Flex catheter appears to have an important design flaw. While it passed premarket testing to achieve 510(k) clearance, the boundary conditions and test criteria did not reflect real world use, or the device was not developed to high enough tolerances for real world use. Regardless, the product has an extremely high safety risk that can result in stroke or death. Nothing short of not using the devices will fully protect patients for this risk. Pre-procedural inspection and infactory visual inspection of the catheters are clearly not curtailing this risk. Labeling mitigations will not adequately penetrate to all operators and may be inadequate anyway."
  - Quintessential Capital Management Report, November 10, 2020 "Penumbra and its 'Killer Catheter'"[2]
    - The device is "structurally flawed and prone to critical malfunctioning"
    - Penumbra promotes the use of injecting the contrast media by hand, contrary to labeling changes warning against such use ("Performing contrast injections through JET 7 Xtra Flex is not consistent with the intended use of the product")
- Continuing malfunctions and deaths following minimal attempts to correct design defects through targeted and ineffective labeling changes; indicating failure to follow quality system requirements, including effective corrective and preventative action
  - Evidence Submitted:
    - November FDA Adverse Event database: reports seven new Jet7 injuries, another Jet7 death, and significant number of malfunctions.
    - Latest death made public on December 2, 2020, please see links below.
      - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10850869&pc=NRY
      - https://www.bloomberg.com/news/articles/2020-12-04/catheter-linked-death-jolts-penumbra-a-target-of-short-sellers
- Manufacturer may have knowingly deceived FDA, as evidenced by a complicated scheme to create a fake persona to serve as author on significant number of Penumbra related clinical studies; Indicating literature review Penumbra used to support the determination of substantial equivalence by leveraging clinical outcomes from devices that are considered technologically equivalent contained significant fraudulent documents; Suspect that financial disclosure made to FDA throughout the years have been fraudulent or inaccurate given the extensive publications by the fake Dr. Antik Bose.

[1] Attachment 1
[2] Attachment 2

- Evidence Submitted:
  - Quintessential Capital Management Report, December 8, 2020 "Is Penumbra's Core Scientific Research Authored by a Fraud"[3]
  - Please see the Summary for K173761, clearly indicating the importance of the literature review in establishing substantial equivalence for the Jet7 model series.

[3] Attachment 3