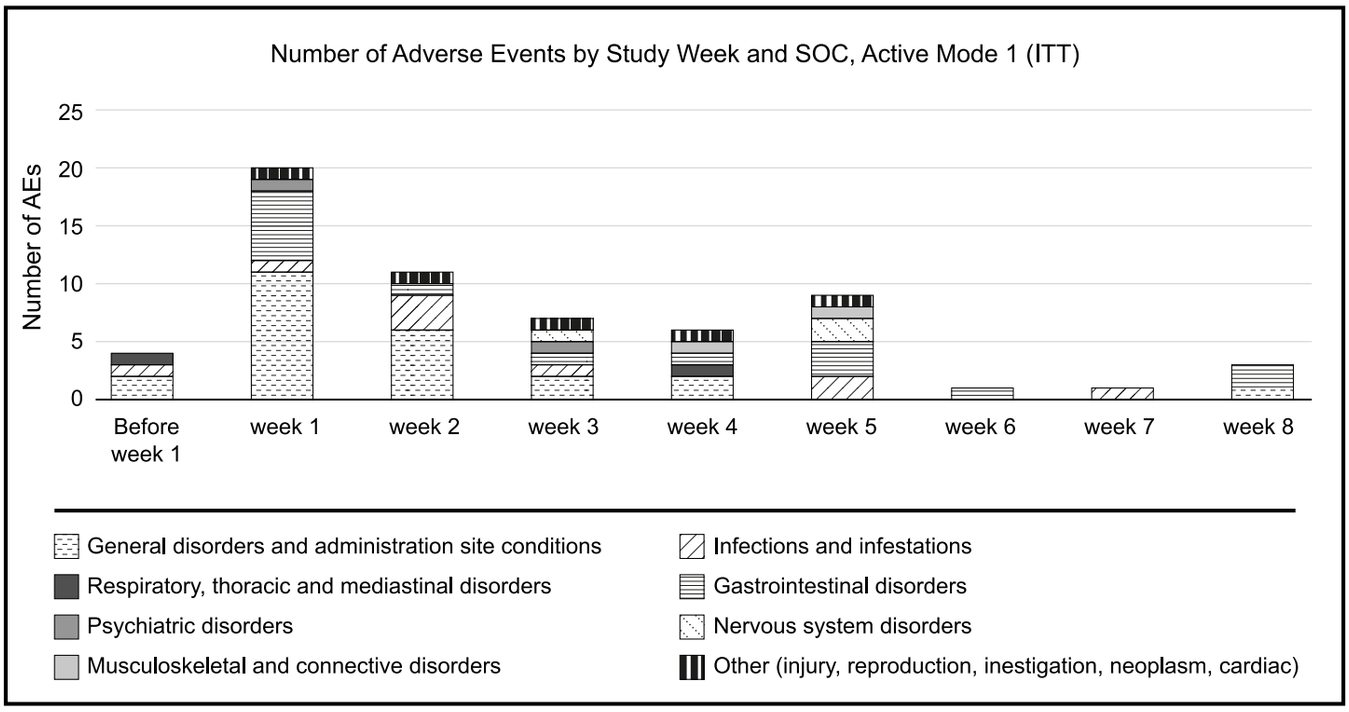
A post-hoc time to adverse event analysis demonstrated a higher prevalence of adverse events early in the study and a declining trend over the 8-week study.

Figure 1: Adverse events by study week and system organ class (ITT)



Additional Clinical Information

Five (5) clinical trials were conducted prior to the V270 pivotal study. The studies included a total of 499 subjects and may have varied from the V270 study treatment protocol in the dosing regimen, number of Capsule vibration sets while passing through the large intestine, and the number of Capsule administered per week. The prior studies are unable to support effectiveness of the Vibrant System. However, FDA considered the cumulative safety data in these studies to support safety of the Vibrant System. Safety data from these prior studies are consistent in the type, severity and frequency of adverse events reported in the V270 pivotal study.

7. Pod Firmware Update

The information in this section is only being provided to inform the end user of the background update process. Pod firmware updates can be performed at any time. Only authorized Vibrant staff are able to perform Pod firmware updates; updates are not intended to be performed by the end user.

As part of the daily communication initiated by the Pod, the Pod always provides its current firmware version number. In case there is a newer version, the cloud will identify it, and will instruct the Pod to start a firmware update process. The update process starts with a download of the encrypted firmware file. Once the new firmware files are extracted, and only after Pod's verification, the new firmware will become active.

Note that the patient is not required to take any action as part of the above process.