Appendix 5.3.1
Comparison of Pilot, Pivotal, and Post-Marketing Studies to Trials in the Pharmaceutical Industry

Category of Device Study	Overview	Comparison to Pharmaceutical Trials
Pilot Studies	Performed to collect initial information about a device's use in humans before a larger-scale clinical study is launched. Also used to validate trial management processes and logistics or to evaluate device design. Often limited to a single center or a few centers and relatively small number of subjects. Carried out when there is little or no experience using the device in humans. However, pilot studies can be used at any point in the life cycle of a product when research, marketing, or design objectives cannot be met without additional clinical data.	Similar to Phase I pharmaceutical trials in which researchers test an experimental drug or treatment in a small group of people (20 to 80 individuals) for the first time to evaluate its safety, determine a safe dosage/manner of usage, and identify side effects.
Pivotal Trials	Typically larger, controlled studies designed to test specific hypotheses that support the submission of a PMA application for a new device, a conformity assessment for CE mark registration in Europe, or a 510(k) premarket notification when *significant* clinical data are necessary to establish substantial equivalence.	Similar to Phase II and III when the experimental study drug or treatment is given to a larger group of people (100 to 300 individuals) to see if it is effective and to further evaluate its safety. Note: Phase II and III activities are commonly combined into a single medical device pivotal study, but rarely involve as many subjects as a pharmaceutical trial. Phase II pharmaceutical trials typically involve 100 to 300 patients, whereas Phase II trial can include thousands.

Category of Device Study	Overview	Comparison to Pharmaceutical Trials
Post-Marketing Studies	Often required as an approval condition for a PMA, but generally not required for a 510(k). Usually imposed to analyze the ongoing safety of a new device, but can also be used to study other issues. For example, a trial with a narrow scope might be used to gather additional data on a specific safety or performance issue. Another study might compare alternative treatments to support comparative effectiveness claims or failure analysis investigations.	Post-marketing studies are similar to Phase IV pharmaceutical trials used to delineate additional information, including the drug's risks, benefits, and optimal use. Post-marketing device studies and Phase IV clinical trials provide the most directly equivalent comparison between device and drug studies.

