The purpose of this policy is to outline the Performance Evaluation Process used by Stable Orthopaedics Pty Ltd.

This policy applies to any registered medical device that has been registered by Stable Orthopaedics Pty Ltd as the sponsor.

Post-Market Surveillance (PMS) is a collection of processes and activities used to monitor the performance of a medical device. These activities are designed to generate information regarding use of the device to expediently identify device design and/or usage problems and accurately characterize the real-world device behavior and clinical outcomes.

Stable Orthopaedics Pty Ltd undertakes this task yearly with the help and support of each manufacturer for which Stable Orthopaedics Pty Ltd acts as the sponsor within Australia and New Zealand.

For Australia the process followed is as per and using a template spreadsheet:

https://www.tga.gov.au/new-compliance-dashboard-post-market-medical-device-reviews

For New Zealand the process followed is as per and is only related to safety after collection of PMS data for Australia:

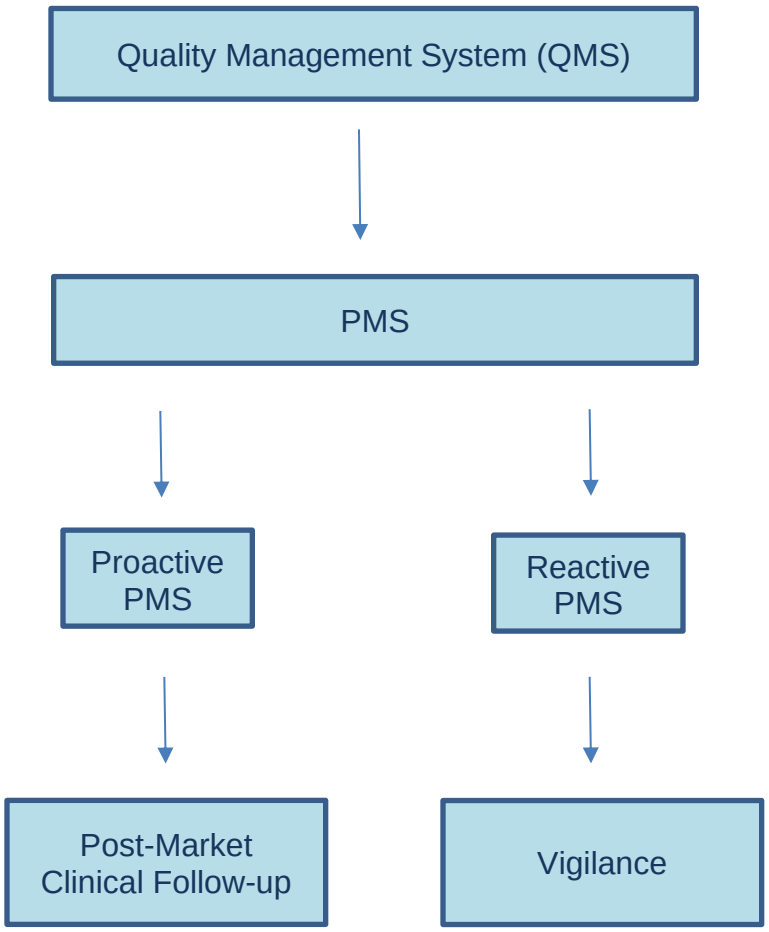
https://www.medsafe.govt.nz/regulatory/DevicesNew/safety-monitoring.asp

Table and Figure 1 provides a high-level view of what is undertaken and how, using the above links to submit actual data and findings.

Table 1: Examples of Post-Market Surveillance (PMS) data and their respective action types

Proactive	Reactive
• Customer surveys • Post CE mark clinicaltrials, including Post-Market Clinical follow-up (PMCF) • Manufacturer sponsored device tracking/implant registries • Expert user groups (focus groups)	• Customer complaints • Unsolicited user feedback (other than complaints) • Maintenance/service reports • In-house testing (routine) • Failure analysis • Social media • Literature reviews • Regional or national device registries (non-manufacturer sponsored trials)

Figure 1: Relationship Between Quality Management System (QMS) and PMS



Document history and change record

Issue	Issue date	Description of change
1.0	May 2020	Initial Issue
2.0	March 2023	Reviewed no Changes