FDA 510(k) Hearing Minutes Excerpt

January 2020

"Dr. G explained that the questions regarding the applicability of the CQI data in questions 3 a-d of the AINN letter for K1917xxxxxx stemmed from the legal team at the FDA. The Agency was originally under the impression that these data were from a clinical investigation.

Dr. Ramshaw provided clarification that these data, which he has submitted for publication, were obtained through a CQI process complying with all applicable regulations and patient informed consent requirement for these efforts. Patients were informed of the CQI process and allowed to choose whether to receive any particular treatment option, including the type of mesh. It was further clarified that these data are real-world evidence collected by Dr. Ramshaw as part of his surgical practice at his institution and not as part of a clinical study or to prove a hypothesis. Rather, the CQI process presents and analyzes real-world evidence in an effort share and collaborate, and to periodically analyze the data to provide feedback loops for the clinical team for learning and improving outcomes. During this particular CQI effort, use in a contaminated field occurred in about 1/3 of the patients. Approximately twenty five percent (25%) of patients received other meshes (instead of or in addition to XXXX mesh) and 1 patient had hernia repair without a mesh (based on the patient's choice).

Dr. G commended Dr. Ramshaw on his efforts and noted that **these efforts to provide real-world evidence through CQI process and publications are important to understanding patient care**.

Dr. G concluded that **the CQI data used to support K1917xxxxxx could be justified since it was not a clinical study**; rather a real-world data collection effort where patients were properly informed and consented as part of standard surgical practice at Dr. Ramshaw's institution. The Sponsor agreed to clarify these points in their response to the AINN letter questions 3 a-d. Dr. N agreed since these data were not gathered as part of an investigation."

→ **Conclusion**: All requested indications and contraindications included in the 510(k) submission were approved because of the real-world CQI data provided by CQInsights.