Medical Device Reports

The Context
Device manufacturers must make Medical Device Reports to FDA based on the requirements in 21 CFR Part 803. FDA requires a report for every event that involves a a) death, b) a serious injury, or c) a malfunction that could involve a subsequent death or serious injury.

The Warning Letter
FDA sent this December 22, 2015 Warning Letter to ARB Medical, LLC a manufacturer of polymeric surgical meshes. The Warning Letter was the result of an FDA inspection.

The Issue Cited
The Warning Letter cited a failure to make a timely report to FDA as required by 21 CFR §803.50(a)(2). The citation says, "Complaints FER-010, FER-008, and FER-006 describe a malfunction of your firm's long term implantable device. As a result of the malfunction, the patient had to undergo revision surgery that resulted in the removal of the device or removal of a portion of the device. Your firm should have submitted a MDR for each of the above referenced complaints."

FER-008 involved patient discomfort approximately eight months after implantation. The physician removed the device and upon removal it was observed that the device had a broken cable.

The Warning Letter does not include the details of FER-006 and FER-010.

The Requirement
The MDR regulation, cited in the Warning Letter requires, "[Y]ou must report to [FDA] no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market … has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."

Recommendations
Develop a comprehensive program to receive complaints and evaluate them for reportability under the MDR regulations in Part 803. In particular, review and investigate malfunctions.

For each of these complaints, initiate an MDR Event File.

In the absence of compelling contradictory evidence, file an MDR!