FDA issues new final guidance on Medical Device Reporting requirements

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Medical Device Alert

On 8 November 2016, the Food and Drug Administration (FDA or the Agency) issued a final guidance document entitled *Medical Device Reporting for Manufacturers*[1], which represents FDA's current thinking on the Medical Device Reporting (MDR) regulation's recordkeeping and reporting requirements applicable to medical device manufacturers. The final guidance supersedes FDA's draft guidance released on 9 July 2013, and its previous final guidance on this topic that was issued nearly 20 years ago in March of 1997.

The final guidance is structured similarly to the 2013 draft guidance, in a question-and-answer format, with sections addressing: (1) reporting requirements; (2) written procedures, recordkeeping, and public disclosure; (3) specific issues and situations; and (4) completion of the MDR report form. It is important for manufacturers to understand FDA's requirements and expectations with respect to the MDR regulations as failure to file such reports (and in a timely manner) can lead to significant enforcement actions.

Of particular note is FDA's return to the 1997 guidance's general concept of the so-called two-year "presumption" rule for reporting device malfunctions, with some modification which was absent from the 2013 draft guidance document. According to the new final guidance:

- The 1997 guidance stated that once a malfunction has caused or contributed to a death or serious injury, a presumption that the malfunction is likely to cause or contribute to a death or serious injury has been established. This presumption will continue until either: (i) the malfunction has caused or contributed to no further deaths or serious injuries for two years; or (ii) the manufacturer can show through valid data that the likelihood of another death or serious injury as a result of the malfunction is remote.
- Although the 2013 draft guidance proposed a more stringent application of the "presumption" rule, in the 2016 final guidance, FDA states "[w]e continue to recommend that a firm develop valid data or information specific to the device and malfunction to support a conclusion that the malfunction is no longer likely to cause or contribute to a reportable death or serious injury if it were to recur."
- The 2016 final guidance contains new language that states that "FDA recommends that you submit a notification to FDA with a summary of the data and the rationale for your decision to cease reporting at the end of two years" and provides the expected content of and process for submitting such notifications.

- Alternatively, the guidance points out that the firm may request an exemption from further reporting sooner than two years if the firm's analysis of the data supports the conclusion that the malfunction has not caused or contributed to further deaths or serious injuries and that the likelihood of another death or serious injury occurring as a result of the malfunction is remote.

The final guidance also made a change to how the date of the MDR report is indicated, making it easier to determine the relationship between the date of the alleged event and the date of the MDR report (which has often been the source of much confusion).

The issue of MDR reporting remains complex, nuanced and fact-dependent. There are a number of areas that often trigger questions from device manufacturers, to which the final guidance document provides information in order to help manufacturers understand FDA's current thinking on these topics, including:

- When a delay in surgery is reportable;
- The reportability of events based on the regulatory status of the device in the United States, and where the alleged event occurred;
- The reportability of event types that are addressed in product labeling;
- The reportability of events that are believed to be due to user error;
- When foreign manufacturers and importers may need to submit reporting exemption requests; and
- Reporting expectations for implantable and life supporting and life sustaining devices.

Companies are urged to revisit their MDR reporting practices and procedures in light of the issuance of the new final guidance document; obtain information on best practices; and continue to monitor FDA public statements and actions that may shed additional light on the interpretation and enforcement of the MDR regulations.

While the Agency does not solicit public comments to revise a final guidance document, general comments on this guidance may be submitted to docket number FDA-2013-D-0743. In addition, FDA will hold a webinar to discuss the final guidance on 30 November 2016. Webinar details can be found **here**.

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[1] Available at: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm359566.pdf

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