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FDA's New Communications and Compliance Tool for Device Data Integrity Concerns

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The Food and Drug Administration (FDA) has updated its website to provide new information on data integrity concerns relating to medical devices.

The FDA has expressed data integrity concerns about testing labs in the past year and has issued warning letters to certain testing labs for violations of good laboratory practices (GLPs). This new website page, "Notifications on Data Integrity—Medical Devices," and the publication of a "General Correspondence Letter," may signal a new tool for communicating compliance concerns about testing labs to the regulated industry.

For further analysis, please read our client alert here, which covers the FDA's update in greater detail.

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