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ALERTS

FDA Issues Final Guidance Documents On Medical Device Data Systems And Medical Mobile Apps

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The FDA recently issued two final guidance documents signaling its intention either not to regulate, or to give minimal oversight, to two categories of medical devices, medical device data systems and medical mobile apps. The guidance on medical device data systems bears the wordy title, "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices." The app guidance is titled simply, "Medical Mobile Applications."

The data systems guidance defines "medical device data systems" as "a hardware or software product that transfers, stores, converts formats, and displays medical device data" and cites 21 CFR 880.6310 for a somewhat more elaborate definition. In perhaps record brevity, the substance of the guidance is expressed as follows:

> The FDA does not intend to enforce compliance with the regulatory controls that apply to the following devices:
>
> - MDDS subject to 21 CFR 880.6310,
> - Medical image storage devices subject to 21 CFR 892.2010, and
> - Medical image communications devices subject to 21 CFR 892.2020.

The guidance notes that a medical device data system (MDDS) "does not modify the data, and it does not control the functions or parameters of any connected medical device. An MDDS does not include devices intended for active patient monitoring."

The medical mobile app guidance states that it was changed from a prior final version only to be made consistent with the MDDS guidance. Our prior alert summarizing the medical mobile app guidance can be found here.

Copies of the final guidance documents can be found here and here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device Group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com or Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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