

Bradley Merrill Thompson Quoted "FDA Approves DexCom Share Update, Downclassifies CGM Accessory"

The Gray Sheet

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Bradley Merrill Thompson, Member of the Firm in the Health Care and Life Sciences practice, in the Washington, DC, office, was quoted in *Pharma & MedTech Business Intelligence's The Gray Sheet*, in "FDA Approves DexCom Share Update, Downclassifies CGM Accessory," by Ferdous Al-Faruque. (*Read the full version — subscription required.*)

Following is an excerpt:

"This is indeed confirmation that FDA was serious in its accessories guidance in saying that it would be willing to downclassify low-risk accessories in response to a de novo request," said Bradley Thompson, a spokesperson for the mHealth Regulatory Coalition. "While there may only be a few companies that are interested in this particular technology, the FDA's action displays a much broader willingness to treat accessories reasonably."

At the same time, Thompson believes it might have been better if FDA could have initiated this classification without a company like DexCom having to proceed through a full de novo process, which now opens it up for competitors to enter the market with much less regulatory burden.

"Dexcom had to undertake undoubtedly considerable expense to put together the de novo submission, and my hat is off to Dexcom for basically blazing the way for its direct competitors to follow," said Thompson. "Unfortunately, not many companies are

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so willing to subsidize their competitors.”