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The 2018(ish) FDA "De Novo" Cleared Medical Device Holiday Buying Guide

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The holiday season is usually the time when consumers look for the best deals on the familiar range of consumer electronics – televisions, computers, tablets, mobile devices, and connected speakers. It may be time to add FDA-cleared medical devices to the list. As consumer electronics have become smaller, more powerful, and more connected, and as manufacturers continue to look for new uses for existing technology, they have begun to develop consumer electronic products with intended health benefits. For some products, manufacturers have even gone so far as to have their devices reviewed by the FDA. That's right, that shiny new electronic device that you heard about may be an FDA "cleared" medical device – assuming it is even available this year. Nonetheless, headlines often get way ahead of actual availability.

For the devices discussed below, FDA granted "De Novo" clearance, which is a regulatory pathway for low- to moderate-risk devices that are novel and for which there are no prior legally marketed devices. Lawyers and manufacturers familiar with FDA regulations will likely understand that there are many important practical and legal differences between FDA "approval" and the various pathways for FDA "clearance." The media does not often appreciate these distinctions, and most non-lawyers will not either.

For non-lawyer friends and family members wondering what it means that FDA "cleared" their device – but not wanting a CLE on the subject – it should be sufficient to tell them that most medical devices used in the United States are FDA "cleared" and that, as with most devices, FDA did not require the rigorous pre-market testing that would have been required had FDA "approved" the device. That does not mean the device will not function as intended. The "as intended" part is important because consumers may have no informed or realistic expectations about what the product is supposed to do.

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APPLE WATCH SERIES 4

Apple recently obtained FDA "De Novo" clearance for what most consumers would think of as a heart-rate monitor (electrocardiogram - "ECG") feature on their new **Apple Watch Series 4**. This should not be confused with the simple heart-rate feature found on many "fitness" wearables or exercise equipment. ECGs are considered a gold-standard diagnostic tool for many heart issues. In clearing the device, FDA stated that the "feature analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provides a notification to the user."[2] Doctors and patients alike will no doubt see the appeal of having ECG warnings and results so readily available.

Although FDA previously cleared over-the-counter ECG devices, including **AliveCor's KardiaBand** watch band for the Apple Watch, Apple has built the ECG feature into the watch itself. That makes the Series 4 the first large-scale wearable consumer electronics product to itself be an FDA-cleared medical device.

Although the appeal of the ECG feature seems obvious, FDA's clearance letter makes a number of critical points that are important to consumers. As with any medical device:

- It is important to understand how it functions. FDA states "the feature is intended to opportunistically surface a notification of possible AFib when sufficient data are available for analysis. These data are only captured when the user is still." In other words, it is not intended to check a user's heart rate during active exercise.

- It is important to understand whom it is supposed to help. For example, FDA states: "The feature has not been tested for and is not intended for use in people under 22 years of age." Also, FDA states: "It is also not intended for use in individuals previously diagnosed with AFib." This seems like a critical caveat, because the millions of Americans previously diagnosed with AFib may presume that the Apple Watch Series 4 is meant to help them.

- It is important to understand its limitations. FDA cautions "[i]t is not intended to provide a notification on every episode of irregular rhythm suggestive of AFib and the absence of a notification is not intended to indicate no disease process is present."

- It is important to understand potential risks. In this case, FDA is concerned with

2 https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180042.pdf

"misinterpretation and/over-reliance on device output," "false negative" results, and "false positive" results.

It is unclear how much these potential risks should worry consumers, but FDA is very clear that the Apple Watch ECG feature "is not intended to provide a diagnosis" and is "not intended to replace traditional methods of diagnosis or treatment." The take-home message for consumers is that the Apple Watch (and/or the KardiaBand) cannot replace doctors and professional medical care.

One very important final note for shopping this holiday season: although Apple built the ECG hardware into the Apple Watch Series 4, it had not released the software as of OS 5.1. Apple's website currently says to expect that app to launch "later this year."

BOSE HEARING AID

Bose is best known for their headphones and high-quality home theater speaker sets, but they have also entered the consumer medical device business. In October 2018, Bose obtained FDA "De Novo" clearance for the **Bose Hearing Aid**, a wireless device intended to amplify sound for those over 18 with mild to moderate hearing loss. Like the Apple Watch's ECG feature, the Bose Hearing Aid breaks new ground as the first FDA-cleared hearing aid that is intended for users to fit, program, and control without assistance from a health care provider. Also, like the Apple Watch ECG feature, the Bose Hearing Aid can be controlled though an app.

The market for such a device is huge – FDA estimates more than 37 million Americans over 18 have some trouble hearing. FDA states that clinical studies found the Bose Hearing Aid to yield comparable outcomes relative to those found using a professional fitting. At least for the immediate future, however, almost all of the Americans who might benefit from this device would still need to see a health care professional in order to obtain it. That is because FDA has never issued regulations establishing a category for "over-the-counter" ("OTC") hearing aids. FDA is not expected to even propose those OTC regulations until the summer of 2020. Although FDA eliminated the federal "physician waiver" requirement in late 2016, most states still require that hearing aids be obtained through a health care professional.

Apple and Bose are surely only two of what will be many consumer electronic giants that will enter the market with FDA-cleared medical devices in the near future. There

is no question that the marketing of medical devices directly to consumers will broaden the range of product liability issues that traditional pharmaceutical and medical device manufacturers face, as well as raise novel issues and challenges to be addressed by the courts. For now, lawyers most interested in providing advice to family members about what to buy for the holidays should make sure everyone is focused on the right products. A "heart rate" monitor is not an FDA-cleared ECG, and consumers that purchase any Apple Watch other than a Series 4 watch are not purchasing a FDA-cleared device. Bose currently makes headphones, "Bose Hearphones," which it suggests will help consumers "Hear Better," but that product is not the FDA-cleared Bose Hearing Aid device and consumers won't be able to buy such products online. So perhaps the best recommendation this Holiday Buying Guide can make, at least for 2018, is this: Proceed with caution.

Questions or Information

If you have any questions about this alert, please contact Adam M. Masin at amasin@goodwin.com.

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