Weekly Whitepaper
Week #10

Wearables – Avoiding the FDA

It's *not* a Medical Device!

Not only are electronics getting smarter, they are also getting smaller and lighter. As wireless communication has improved, and product sizes have shrank, a new category of "wearable" electronics has emerged. This new product category is expected to be one of the fastest growing segments within the field of consumer electronics. Initially dominated by fitness trackers, many new forms of wearables are now being developed including smart glasses, intelligent fabrics/clothing, and even smart patches worn directly on the skin.

Within the wearables category are the fitness trackers and other devices that monitor a user's fitness, well-being, and health. Many new products have been introduced to the market that provide medical information to the user, but are not intended to be medical devices. The fear of course for manufacturers of these devices is the oversight of the US-FDA.

The good news is that the FDA doesn't really want to review these types of products. To help define which types of wearable products are considered "Medical Devices" subject to the rules and regulations of the FDA, official FDA guidance documents have been published. The FDA has recently published:

- "General Wellness: Policy for Low Risk Devices" – this document defines "wellness" products that do not fall under the FDA's jurisdiction and,
- "Mobile Medical Applications" for guidance to the mobile app developer.

By following these guidance documents, manufacturers of wearable electronics can avoid the rules and oversight of the FDA. In questionable cases, it is even possible to present your position to the FDA and get an official ruling – this can be done as early as the product concept stage.

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