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Lenient regulations for digital medical devices

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Lenient regulation for digital medical devices

The USA Food and Drug Administration (USFDA) has issued a new guidance that exempts medical devices from its regulatory scope. This means that the makers of these devices, some of which are connected to apps, no longer have to go through the FDA's review process before they bring their product to the market.

The affected devices are largely clinical, including things like anesthesiology, cardiovascular, and dental. But a number of consumer mobile and digital health products are exempted as well, including thermometers, stethoscopes, talking first aid kits, hearing aids, fertility diagnostic devices, and exercise equipment.

"The FDA believes that these devices are sufficiently well understood and do not present risks that require premarket 21 notification review to assure their safety and effectiveness," the FDA said in the advisory.

"This is big news, and a huge boost to the mHealth industry. It shows that FDA is being extremely practical in reviewing its own practices and updating its regulatory requirements where the risks simply do not merit the investment of regulatory resources," said Mr Brad Thompson, Epstein Becker Green compliance attorney.

The FDA will now open a 60-day comment period before issuing a final ruling on the matter.