BioSpectrum the business of Bio & Health Sciences

US FDA issues medical device security guidelines

12 October 2014 | News | By BioSpectrum Bureau

FDA issues medical device security guidelines

In an effort to bolster the security of medical devices, United States of Food and Drug Administration (US FDA) has published a new set of recommendations. The new standards suggests that manufacturers take into account cyber security risks as part of the design and development of a medical device. It has asked device makers to submit documentation to the FDA about identified risks and existing controls to mitigate those risks.

The FDA also recommends that manufacturers submit their plans for the updation of existing operating systems and medical software.

However, these new guidelines will not change the existing approval process or the time line for device approval, said the regulatory body.

Dr Suzanne Schwartz, director of emergency preparedness/operations and medical countermeasures at the FDA's center for devices and radiological health said, "It is important for medical device manufacturers to remain vigilant about cyber security and to appropriately protect patients from those risks," in a statement.