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Unique Device Identification regulations for medical devices

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Singapore: The Food and Drug Administration (FDA) has issued a proposed regulation to establish a unique device identification (UDI) system for medical devices marketed in the USA. UDI system was mandated by Congress in 2007 but still is not in place. Legislation passed by Congress in June requires the FDA to implement the UDI system for high risk, life sustaining and implantable medical devices within two years of finalizing the regulations.

Consumers Union, the policy and advocacy division of Consumer Reports, applauded the FDA for issuing the proposed regulations, while noting that it was still reviewing the draft rule. Consumers Union will file formal comments to the proposed regulations later this year.

"These regulations are long overdue and are critical for protecting patients from faulty and dangerous medical devices," said Ms Lisa Swirsky, senior policy analyst for Consumers Union, the policy and advocacy division of Consumer Reports. "Effective post-market surveillance of medical devices depends on having UDI in place. Once it is fully implemented, this system will enhance the FDA's ability to identify problem medical devices more quickly and inform patients when their safety is at risk."

For most medical devices, the UDI will include a device identifier, which is a unique code tied to a specific device model, and a production identifier, which includes production information for the device. The FDA has proposed phasing in the implementation of the UDI system beginning with the highest risk medical devices first. Low risk devices will be exempt from some or all of the regulations. The FDA is seeking public comment on the proposed regulations for 120 days.