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Taiwan revamps medical device management system

May 12, 2021 | News

A new era for the management of medical devices began on May 1st, 2021 by amending its "Medical Devices Act"



Taiwan has announced the new "Medical Devices Act" to establish a system to effectively regulate medical devices throughout the medical device life cycle, marking a new start for medical device management in Taiwan. A new era for the management of medical devices began on May 1st, 2021.

Following world trends, Taiwan has amended the Pharmaceutical Affairs Act and stipulated a new law specifically for the management of medical devices. The new Act covers repair and maintenance of medical devices, sale and supply of medical devices, quality management system and distribution management of medical devices, electronic listing system for some low-risk products, flexible validity period for issuing licenses, medical device clinical trials, safety monitoring of medical devices, proactive reporting and more, to protect consumer safety and improve management of medical devices.

According to Taiwan Food and Drug Administration (TFDA), at present, TFDA has completed the drafting of relevant regulations and regulatory orders related to the Medical Devices Act, including Regulations Governing the Classification of Medical Devices, Regulations Governing Issuance of Medical Device License, Listing, and Annual Declaration, Regulations of Medical Device Tracking Management, and Regulations for Management of Medical Devices Technicians. The government has also introduced various measures to give medical device firms a reasonable transition period to make adjustments and to minimize the impact to the industry.

Director-General Shou-Mei Wu of TFDA states that Taiwan's medical device management system will continue to follow international trends. Taiwan will work to harmonize with international regulations and reduce regulatory barriers that Taiwanese medical device dealers face when they attempt to compete in the international market.