[MDREX Newsletter] Amendment to the Notice of New Category of Medical Devices

The Ministry of Food and Drug Safety (hereinafter referred to as the MFDS) in Korea determines and discloses medical device categories and classes of each medical device through the "Regulations on Medical Device Categories and Class by Item (MFDS Notice)". Thus if a product that is imported into Korea is deemed a medical device, it is necessary to check the category and class of such device in order to proceed with the necessary approvals/certification/notification procedures and KGMP certification. As a reference, the number of categories specified in the Notice is currently limited to about 2,600 categories, but the following categories have been newly established through the recent amendment of the Notice. Therefore, if your company manufactures relevant products, please check the requirements on the approval process for such products through a class check.

- E 12010.01 Skin cancer image detection/diagnosis auxiliary software [Class 3] skin cancer imaging, computer aided detection/diagnostic software; After detecting skin cancer in suspected areas as medical images, display such image outlines, colors, or indicator lines, or determine the presence or absence of skin cancer and the severity of skin cancer or software used to assist medical personnel in making diagnostic decisions by automatically displaying information about the likelihood of skin cancer, etc.

- E 10030.01 Musculoskeletal system rehabilitation software [Class 2] Musculoskeletal system rehabilitation, software: Software used for muscle reconstruction and joint motion recovery by analyzing gait function and providing rehabilitation information to the user. Includes virtual/augmented (VR/AR) based software.

- E 08040.01 Eye movement analysis software [Class 2] Eye movement, analysis software : Software used for diagnosis and analysis of eye movements. Includes virtual/augmented (VR/AR) reality-based software

- E 03060.01 Speech-voice disorder diagnostic aid software [Grade 2] Speech, voice, computer aided diagnosis software: Software used to analyze language and voice data to assist medical professionals in making diagnosis decisions

- A 79160.08 Closed direct drug delivery system [Class 2] Closed antineoplastic, hazardous drug reconstitution, transfer system; When transferring anticancer drugs and other toxic drugs from a container to another container, hazardous substances are released into the air in a closed connection with the container system used to prevent leaks etc.

In addition, table 1 in the annex of the Enforcement Rules of the Medical Devices Act permits medical device manufacturers to request a designation of category and class for new devices not designated currently within the MFDS categories/classes. Therefore, if your company would like to enter the Korean market and introduce a new device, or adjust classes for an existing device, please contact MDREX (pro@mdrex.co.kr).

Kind regards,

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