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강연제목: 유럽의 임상평가 및 국내도입방안

European clinical evaluation and Introduction of a domestic clinical evaluation system.

Abstract:

Objective: In 2017, the European Medical Device Act changed the existing Medical Device Directive to Regulations and strengthened clinical evaluation. Consequently, discussions regarding the introduction of clinical evaluation are emerging in Korea as part of efforts toward international regulatory harmonization. ***Methods:*** For the literature search, the medical device clinical assessment system was searched using Ovid-Medle, Ovid-EMBase, COCHRANE, etc.; a manual search was performed on Google Scholar. In addition, an online perception survey was conducted on a total of 135 manufacturers and importers with a total of 28 questions in three areas: i) general responses to manufacturers and importers.

Results: As Europe switched to medical device regulation (MDR), the adequacy of clinical evaluation reports for high-risk medical devices, including Class III and some Class IIb devices, should be evaluated by a panel of experts and third-party certification agencies. European clinical evaluation system should be introduced to achieve international regulatory harmonization. However, it was also noted that the structural characteristics of the domestic medical device industry, infrastructure development, and continuous support system must be considered.

Conclusions: It is important to establish a medical device lifecycle management system that adheres to international standards, specifically by implementing a clinical evaluation system in line with the European MDR. Moreover, it is necessary to periodically and continuously evaluate developments in various fields that affect the medical device industry, infrastructure, and support systems.

Brief Biosketch

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