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국문 강연 제목: 기계 학습 가능 의료기기의 규제와 그 이슈

영문 강연 제목: Machine Learning enabled Medical Devices Regulation and  
Challenges

#### Abstract

Medical devices are regulated medical products and should be strictly approved by regulatory authorities before entering the market. In the process, their intended use and performance are verified, and they can only be used in the clinical field within the scope of the authorization. In recent research, AI models such as large-scale language models and vision-language models have become huge, and the general use of generative AI has become possible, and the consistency with the existing regulatory framework has begun to be inconsistent. The purpose of this presentation is to share recent research trends related to generative AI as medical devices and to highlight issues in the regulatory framework.

#### Brief Biosketch

이충근 박사는 연세대학교 의공학과에서 학사를, 전기전자공학과에서 석박사를 받았습니다. 현재는 식품의약품안전처에서 인공지능 의료기기 등 시판 전 허가를 위한 심사 업무를 담당하고 있으며, 국제 의료기기 규제 당국자 포럼 (IMDRF)의 인공지능/기계 학습 의료기기 실무 그룹에 참여하고 있습니다.

Dr. Chungkeun Lee received his bachelor's degree from Yonsei University's Department of Biomedical Engineering, and his master's degree and doctorate from the Department of Electrical and Electronic Engineering. He is currently in charge of the review process for premarket approval of AI/ML enabled medical devices at the Ministry of Food and Drug Safety (MFDS) and participates in the AI/Machine Learning Medical Devices Working Group of the International Medical Device Regulators Forum (IMDRF).