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생성형인공지능 기반 의료기기의 사이버보안 규제이슈 Regulatory Cybersecurity Issues for Medical Device based on Generative AI : a Narrative Review

Abstract(영문):

Generative AI has the potential to enable innovation in various domains and continues to evolve dynamically. In the medical device space, new software as a medical device is being developed that uses generative AI to automatically generate readings from chest X-rays. Medical devices are regulated medical products, and the challenge is that emerging technologies should be reviewed strictly by regulatory authorities in order to enter the market. During this review process, manufacturers should demonstrate reduced risk, but generative AI has different risks compared to traditional software medical devices. In particular, the input/output characteristics via prompting technology and the systemic nature of large-scale models present novel cybersecurity risks that are different from traditional software medical devices. In this talk, we review the literature on cybersecurity risks of generative AI-based medical devices.

Brief Biosketch

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