

Regulatory landscape of AI/ML-Enabled Medical Devices

Surveys of FDA approved or CE marked devices can be found at:

Muehlematter UJ, Daniore P, Vokinger KN. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): A comparative analysis. *Lancet Digit Health* 2021;3:e195-203. DOI: [https://doi.org/10.1016/S2589-7500\(20\)30292-2](https://doi.org/10.1016/S2589-7500(20)30292-2)

Supplement to: Muehlematter UJ, Daniore P, Vokinger KN. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): A comparative analysis. *Lancet Digit Health* 2021; 18 January 2021. [https://doi.org/10.1016/S2589-7500\(20\)30292-2](https://doi.org/10.1016/S2589-7500(20)30292-2).

US regulatory perspective

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EU regulatory perspective

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