

Empatica: Utilizing US data for EU CE Marking



About Empatica

[Empatica](#) is redefining clinical research and remote patient monitoring through medical wearables and digital biomarkers. With 5 FDA clearances and over 100,000 devices deployed, Empatica's tools seamlessly collect and monitor health data from daily life.

Relevant product: [EpiMonitor](#) is the latest iteration of Empatica's flagship wearable, EmbracePlus. It detects possible generalized tonic-clonic seizures and monitors epilepsy. EpiMonitor received US Food and Drug Administration (FDA) clearance, with the European CE marking process underway.



Background

- Empatica's strategy for FDA clearance of EpiMonitor involved leveraging clinical evidence from its original Embrace device clearance, supplemented by data on how EpiMonitor's new hardware achieves the same level of seizure detection.
- While the EU's Medical Device Regulation (MDR) does not call for mandatory clinical study data for Class IIb products, it requires at minimum a clinical evaluation based on data in literature from equivalent devices.



National engagement

- Empatica's experience with the FDA was markedly positive, with a clear and efficient review process that culminated in the rapid clearance of EpiMonitor. In comparison, the European regulatory landscape has proven more challenging.
- Notified Bodies (NB) in Europe vary in their levels of expertise with digital health technologies (DHT) and in resource availability, which can sometimes result in extended and more complex regulatory approval processes.



Key takeaways

- ✓ Successful reuse of clinical evidence from one jurisdiction to another saves time and resources, allowing for more efficient patient access.



Strategy & approach

Instead of conducting a new clinical study, Empatica will leverage clinical and safety data generated for their FDA clearance, post-market surveillance data generated on the equivalent Embrace product, plus a literature review for the EU CE marking process.



Early interactions with a Notified Body to align on technical documentation, clinical evaluation, and clinical data expectations are key for a successful MDR submission.”

— **Alberto Poli**

Director, Quality & Regulatory Compliance, Empatica