Digital Health Solutions

Case Study

Accelerating FDA Clearance for Remote Health Monitoring Devices

End-to-End Product Development and Regulatory Compliance Support for Multiple 510(k) Clearances

OVERVIEW

Digital Health Solutions was engaged by a Boston-based client company for the development and FDA approval for two generations of wearable medical devices . These wearable systems, designed for remote continuous multi-parameter vital signs monitoring from home, required comprehensive engineering, regulatory, and software support to bring them to market. Our responsibilities spanned from engineering development (hardware, firmware, cloud), Design History Folder development, Human Factors, Cybersecurity, Risk Management, Verification and Validation, to final FDA approval, utilizing our expertise in medical device compliance and late-stage product enhancements.

CHALLENGES

- **Fast-track FDA clearance:** The client aimed to secure 510(k) clearance for two generations of Class II devices with limited internal regulatory compliance capabilities.
- **Finalize critical software and ensure compliance:** Connected firmware and cloud systems required completion and validation to meet IEC 62304 and FDA cybersecurity guidance.
- **Close quality and documentation gaps**: The team needed to complete comprehensive documentation and validation reports for FDA submission under time pressure.

APPROACH

- **Regulatory Compliance Support**: Led DHF gap analysis, created FDA-compliant documentation, and managed submission and review, including deficiency responses.
- **Systems, software, and cybersecurity development:** Finalized software, revised electronics, and implemented cellular connectivity with secure data handling and BLE optimization.
- **V&V Testing, cybersecurity, and usability validation:** Delivered full V&V per IEC and ISO standards and led human factors studies to meet FDA expectations.

IMPACT

- **Dual FDA clearances achieved:** Cleared both generations of the device including the initial version for pulse and respiratory rate and second-gen expanded to include SpO_2 and temperature.
- **Accelerated market launch:** Enabled clearance and production on schedule through integrated engineering and compliance support.
- **Delivered scalable, secure solutions:** Devices met clinical, safety, and usability requirements making it ready for broad deployment across US and key international markets

About Digital Health Solutions

DHS, located near Boston, MA, provides key engineering, testing, documentation & regulatory services for Medical Device, Diagnostics, Healthcare and Life Science industries. Our expertise & services include:

- **End-to-end Product Development**
- **Firmware/Software Engineering (AI/ML)**
- **Systems Engineering**
- **Quality & Regulatory Guidance**
- **Cybersecurity**
- **ISO 13485 Contract Manufacturing**
- **Verification and Validation Testing/Documentation**

Accelerating MedTech Innovation

Let's build something together.

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