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F3 Wireless and Sony Add Cellular to FDA-Cleared Migraine Device without Triggering Recertification

A leading medical device company helping migraine patients find real-time relief wanted to add secure cellular tracking to support insurance reimbursement and monitor patient use. The challenge: doing so without altering the device's design or restarting the FDA approval process.

Partnering with Sony, F3 Wireless integrated the ALT1250 chipset to add low-power LTE-M/NB-IoT connectivity and built-in location tracking. The result is a compact, energy-efficient device that connects seamlessly to the cloud for effortless data reporting—preserving FDA clearance and saving months of regulatory time and cost.

Enabling Insurance Reimbursement Through Connectivity

Sony's Altair ALT1250 modem allows the migraine therapy device to automatically log each session and send secure updates to the cloud—meeting insurance requirements for adherence tracking and unlocking reimbursement eligibility.

Automatic Insurance Documentation

Every therapy session is logged and securely transmitted to the cloud. Insurance companies receive the information they need to approve reimbursement without any manual reporting from patients or providers. The device handles documentation automatically.

Smarter Adherence Tracking

With cloud-based reporting, healthcare providers can easily see how patients are using the device. This visibility means providers can reach out if patients aren't using the device as prescribed, and provides objective data to assess treatment success.



Battery Life Preserved

The ALT1250's ultra-low power architecture means that cellular features operate within the existing energy budget. Patients still enjoy multiple therapy sessions between charges, so added connectivity doesn't come at the cost of convenience.

Secure, HIPAA-Compliant Data Transmission

End-to-end encryption and HIPAA-compliant cloud uploads protect patient information. The ALT1250 and HL7800 SDK deliver a secure framework designed specifically for connected medical devices handling protected health information.

The Challenge:

Cellular Integration Within FDA Constraints

The device had already earned FDA clearance for its enclosure, weight, and thermal profile—meaning any physical redesign would require costly re-testing and delay commercial timelines by months.

Constrained Form Factor

The device was optimized for portability and home use with limited internal space. Integrating a cellular radio, antenna, and power management within the shielded housing demanded precise RF engineering, since the layout couldn't change.

Strict Power Limits

The existing battery supported multiple therapy sessions between charges, and adding cellular could not compromise that experience. All new functionality had to operate within the original power budget.

Multiple Certification Requirements

To stay compliant, the updated design needed FCC certification for cellular operation and PTCRB carrier approval—while maintaining FDA clearance. Balancing these overlapping requirements required careful planning and collaboration across engineering and regulatory teams.



The Solution:

Miniaturized Cellular Integration

Sony and F3 Wireless used pre-certified ALT1250 and HL7800 modules and proven test processes to achieve FCC and PTCRB approval—without triggering new FDA reviews. This kept the migraine device on its launch timeline and avoided unexpected engineering and regulatory costs.

Compact Board Design

F3 Wireless designed a miniaturized cellular PCBA around the Sierra Wireless HL7800 module and Sony's ALT1250 chipset, fitting it into unused board space. The team preserved the existing enclosure, tooling, and industrial design, so no mechanical changes—or new FDA submissions—were required.

Integrated System Architecture

Sony's ALT1250 combines the cellular modem, GNSS for location tracking, and security functions in a single compact chip. The integrated iSIM removes the need for a physical SIM slot, and built-in GNSS enables therapy session tracking without extra components—critical in a space-constrained design.

RF Performance Optimization

F3 Wireless co-designed RF circuitry with Taoglas multiband antennas to perform reliably inside the metal-shielded housing. Strategic antenna placement, impedance matching, and testing ensured consistent LTE-M and NB-IoT performance despite challenging RF conditions.

Ultra-Low Power Operation

The ALT1250's power-efficient architecture enabled cellular operation within the existing battery budget. Advanced power-saving modes and efficient data processing kept energy use low, so patients maintained the same multi-session battery life even with connectivity added.

Secure Data Pipeline

Using the HL7800 and ALT1250 SDK, the team implemented encrypted firmware and secure cloud communication for therapy session data. The integrated security framework meets HIPAA requirements without custom development.

The Outcome:

Medical Device Connectivity that Pays for Itself

Sony and F3 Wireless added cellular connectivity without redesigning the device, preserving the original enclosure and tooling. This avoided new FDA testing, kept the launch on schedule, and saved months of development time.

Energy targets were met thanks to the ALT1250's ultra-low-power architecture, so patients still get multi-day therapy sessions between charges. Automatic data uploads now meet insurance payer requirements, unlocking a reimbursement pathway and expanding the device's market potential.

The result is a connected medical device that delivers secure, compliant cellular connectivity while staying within FDA-cleared hardware constraints—enabling new business models without the risk or cost of a full product redesign.

