Digital Healthcare, Medtech, and Software-based Medical Platforms

Intellectual property strategy for digital health, AI-enabled healthcare, and software-driven medical technologies

Digital health and software-based medical technologies increasingly define modern healthcare—powering connected medical devices, AI-enabled diagnostics, remote patient monitoring (RPM), cloud-based clinical decision support, and digital therapeutics. As innovation shifts toward software-first medical device architectures, intellectual property (IP) strategy must align with FDA regulatory classification, data privacy and cybersecurity requirements, and U.S. patent-eligibility standards for computer-implemented inventions.

Marshall Gerstein advises healthcare, medtech, and life sciences companies on IP strategy across the full lifecycle of Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD) products. Our attorneys work at the intersection of medical devices, software engineering, life sciences, and artificial intelligence (AI) and machine learning (ML).

Digital Healthcare, Medtech, and Software-Based Medical Device Technologies
Marshall Gerstein supports IP protection for a broad range of digital healthcare and medtech innovations, including:

- AI/ML software for disease detection or abnormality flagging in radiology (CT, MRI, X-ray) and pathology
- ECG and cardiac-monitoring analytics for arrhythmia detection
- Diabetes-management and insulin-dose decision software
- Digital therapeutics (DTx) for conditions such as insomnia, anxiety, ADHD, and substance-use disorder
- Remote patient monitoring (RPM) platforms using wearable or home-sensor data (blood pressure, pulse oximetry, glucose, spirometry)
- Clinical decision support software for triage, diagnosis, and treatment recommendations
- Rehabilitation software using motion capture or smartphone sensors
- Mobile point-of-care diagnostics using phone-connected devices
- Infusion-pump and drug-delivery control software, including alarm logic and dosing safeguards
- Connected inhaler adherence and dosing platforms
- Ophthalmology and dermatology screening applications
- Cybersecurity, interoperability (HL7/FHIR), and cloud analytics layers supporting connected devices, hospital systems, robotics, software-enabled prosthetics, and orthopedics

These technologies typically fall within **Software as a Medical Device (SaMD)** or **Software in a Medical Device (SiMD)**, as defined by the U.S. Food and Drug Administration (FDA). SaMD and SiMD include digital health platforms, AI-enabled medical devices, clinical decision support software, remote patient monitoring systems, and many FDA 510(k) software products.

FDA Recognition of Digital Healthcare and Software-Based Medical Devices
The FDA has formally recognized the growing importance of software-based medical devices. In its **Digital Health**

Innovation Action Plan (DHIAP), the FDA noted that digital technology—from mobile medical apps to clinical decision-support software—has driven a transformation in healthcare delivery.

The FDA has also emphasized that software-based medical devices introduce new market participants, manufacturing processes, and global distribution models. Because these technologies can impact the health of millions of people, regulatory oversight is essential to ensure safety, effectiveness, and quality.

The FDA distinguishes between two primary categories:

1. **Software in a Medical Device (SiMD):** Software embedded within a hardware medical device
2. **Software as a Medical Device (SaMD):** Standalone software intended to perform one or more medical purposes without being part of a physical medical device

A practical starting point for many digital health products is determining whether the software is embedded in a device or functions independently.

Key FDA Resources

- Software as a Medical Device (SaMD) - FDA overview
- What are examples of Software as a Medical Device? - FDA
- Global approach to Software as a Medical Device - FDA
- How to Determine if Your Product is a Medical Device (includes device software functions, SaMD, and SiMD)
- Artificial Intelligence in Software as a Medical Device - FDA
- Digital Health Innovation Action Plan (PDF; discusses software as a medical device and software embedded in medical devices)

Regulatory classification and intended use influence claim scope, evidence development, and commercialization strategy. Global frameworks, such as the **International Medical Device Regulators Forum (IMDRF) SaMD guidance**, also affect risk categorization and quality-system expectations for multinational IP planning.

How Marshall Gerstein Supports Digital Healthcare and Medtech
Software-based medical device portfolios often require coordinated protection across hardware, software architecture, algorithms, and technical workflows. Marshall Gerstein helps clients develop IP strategies that address patent-eligibility risk and emphasize concrete technical improvements.

Our work commonly includes:

- Patent strategy and portfolio development for digital health, SaMD, SiMD, and connected medical devices
- Drafting and prosecuting patents for signal processing, data processing, and AI/ML-enabled medical technologies with a focus on U.S. patent eligibility
- Prosecution strategies for navigating § 101 rejections and aligning claims with favorable case law
- Design patents for graphical user interfaces (GUIs) and screen-based user experiences
- Freedom-to-operate, invalidity, and infringement analyses supporting product launches, partnerships, and investment diligence
- IP diligence for transactions involving digital health and software medical assets
- Licensing, joint development, and IP provisions for software platforms and data partnerships
- Patent marking counseling, enforcement, and defense for software medical devices and cloud-based platforms, including PTAB and district-court proceedings

Patenting Strategies for Software-Based Medical Devices
U.S. courts evaluate software-based medical device claims under the same subject-matter eligibility framework applied to other computer-implemented inventions. Claims tied to specialized medical device hardware (often SiMD) generally fare better than purely software-focused claims (often SaMD). Across both categories, the strongest patents claim **concrete technical solutions**, not merely desired clinical outcomes.

Effective drafting strategies include:

- Anchoring claims to specific machines or device components when embedded software is involved
- Clearly describing technical improvements to devices, computing systems, or medical technologies
- Framing data- and signal-processing problems in technical terms (e.g., noise, artifacts, latency, false positives/negatives)
- Providing detailed implementation support, including data inputs, preprocessing, feature extraction, algorithm structure, device constraints, and validation protocols

AI-Enabled Digital Health and Life Sciences Platforms
Marshall Gerstein's attorneys work at the intersection of **Artificial Intelligence, digital healthcare, Medtech, and software-enabled medical devices**. AI and ML increasingly drive innovation in diagnostics, imaging, personalized medicine, digital therapeutics, and clinical workflows.

AI-enabled medical devices often rely on large, sensitive datasets and raise issues related to privacy, bias, governance, and lifecycle management. FDA regulatory approaches continue to evolve, particularly for adaptive algorithms that learn from real-world use.

For platform-based products, IP strategy must also address interoperability (APIs, EHR integration), distributed architectures (edge and cloud), and complex ecosystems involving hospitals, payors, device manufacturers, and data partners.

Common IP focus areas include:

- **Data pipelines:** Curation, labeling, de-identification, preprocessing, and quality control
- **Model development:** Feature engineering, architectures, training objectives, calibration, uncertainty estimation, and explainability
- **Deployment:** Edge and cloud architectures, latency, reliability, cybersecurity, and model-drift monitoring
- **Clinical integration:** Human-in-the-loop workflows, decision thresholds, UI design, and post-market change control

Patent Marking for Software Medical Devices
Commercialization strategy should also address patent marking, particularly for software-driven platforms where firmware, applications, cloud services, and third-party devices collectively practice patent claims. Recent IPO Software and Medical Device Subcommittee scholarship highlights that marking requirements can be highly fact-specific and vary by jurisdiction, including the United States, United Kingdom, France, and Germany.

In the United States, proper patent marking can be critical to maximizing damages. The patent statute permits **virtual marking**, typically through a publicly accessible webpage identifying applicable patents (35 U.S.C. § 287(a)). For software products, marking analysis often depends on which components practice claim limitations, how software is distributed (physical device, app store, SaaS), and how marking can be maintained across frequent software updates.

Related Reading

- Marshall Gerstein Insights: The complicated intersection of AI, life sciences and IP
- PatentNext: Patenting Software-based Medical Devices (Part 1)
- PatentNext: Patenting Software-based Medical Devices (Part 2)
- Marshall Gerstein Insights: Patent Marking Regarding Software Medical Devices
- IPO paper: Patent Marking regarding Software Medical Devices (PDF)
- PatentNext: The intersection of AI, life sciences, healthcare, and IP
- PatentNext: Patent marking and software medical devices (IPO paper announcement)