



2026 TRENDS

Medical Devices

TREND 1

Evolving FDA Oversight of Consumer Health and Diagnostic Devices

TREND 2

Expansion of Remote Patient Monitoring Elevates Cybersecurity Requirements

TREND 3

Continued Growth of AI-enabled Medical Devices

TREND 4

Tariffs Impacting Pricing and Medical Device Supply Chains

Over the last year, [medical device](#) companies have continued to innovate and develop more complex products to [diagnose, treat, monitor, and prevent medical conditions](#). The industry is evolving as these devices become smarter, more connected, and increasingly part of everyday life. This is changing how care is delivered, allowing for earlier detection and ongoing monitoring outside traditional clinical settings.

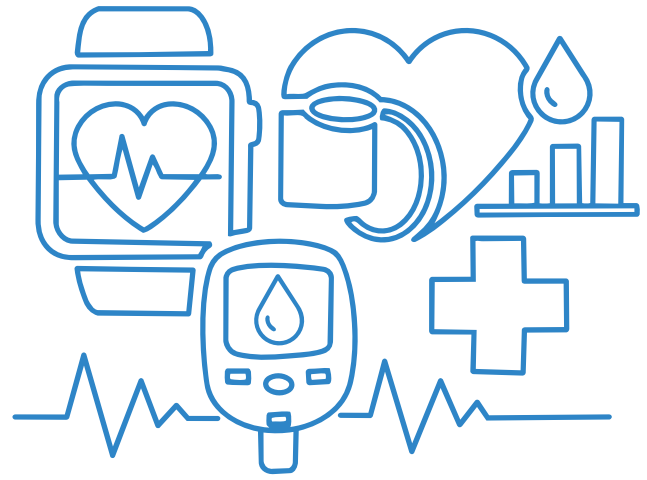
We're seeing consumer electronics that have diagnostic or monitoring capabilities, like the Apple Watch, blur the line between wellness tools and regulated medical devices, prompting the FDA to [update guidance](#) on these devices and raise expectations for safety and validation. Additionally, remote patient monitoring continues to rise, giving clinicians more continuous access to patient data while also calling attention to the need for more robust cybersecurity measures to protect that sensitive data. Artificial intelligence (AI) continues to play an increasingly central role, helping companies improve product development and testing and powering devices that analyze data in real time. And of course, the medical device industry isn't immune to ongoing supply chain uncertainty and evolving tariff policies.

In this report, we dive into the complexity of medical devices today and the impact to the industry in 2026 and beyond.



TREND 1

Evolving FDA Oversight of Consumer Health and Diagnostic Devices



In the last few years, wearable fitness trackers have added novel functionality to [providing health and wellness metrics at patients' fingertips](#). Users can track more than just steps on a watch or hours slept. Wearable devices like the Apple Watch enable continuous [heart rate monitoring](#), track sleep apnea, and capture other critical health metrics. The newest Apple Watch even includes features that allows users [to track blood pressure and identify cases of hypertension](#), which is significant given that [almost 1 billion people worldwide](#) live with high blood pressure, often without a diagnosis.

These new monitoring and diagnostic features have the potential to be lifesaving, especially for undiagnosed conditions. However, as patients receive this health information almost instantaneously, it's imperative that the data and collection methods are accurate.

Apple has worked closely with the FDA on its health-enabled features on the Apple Watch, including [sleep apnea monitoring](#), [irregular heart rhythm notifications](#), and the [hypertension notification](#), which has received FDA approval. Moving forward, companies must invest in regulatory expertise and continue to collaborate with the FDA in such a [rapidly evolving regulatory environment](#).

Over the last several years, consumer electronics have also increasingly implemented health tools that blur the line between wellness products and medical devices. Now, the convergence has extended in the opposite direction, as medical device companies like Dexcom introduce innovations such as the first [over-the-counter continuous glucose monitor](#), Stelo.

Marketed to adults who aren't taking insulin, [Stelo](#) allows individuals to proactively track their blood sugar levels and identify potential risks earlier. For individuals with limited access to care or inadequate health insurance, tools like Stelo can also offer valuable diagnostic insight and increased visibility into their health. According to [the Stelo website](#), the product is marketed toward adults who aren't taking insulin and can be purchased by anyone seeking additional information on their glucose levels.

However, while these technologies can enhance awareness and detection, they're intended to complement, not replace, guidance from a healthcare provider.



TREND 2

Expansion of Remote Patient Monitoring Elevates Cybersecurity Requirements



Wearable devices such as wellness trackers and continuous glucose monitors can now collect and analyze health data 24 hours a day, expanding what's possible with [remote patient monitoring](#): a practice in which patient data is collected at home with healthcare providers accessing the data, providing a fuller view of patient health as opposed to traditional, episodic care.

When health and wellness features are embedded into devices people already use, patients are more likely to stay engaged and actively participate in their own care. Software-enabled devices, including the [Apple Watch](#) and [Dexcom's Stelo](#), enable data sharing with healthcare providers, making it easier for patients and clinicians to view trends over time, supporting earlier detection and leading to more informed medical decisions.



However, this also raises important questions about how that data is shared and protected. As remote patient monitoring becomes more common, it's increasingly important that these systems are capable of safely handling and protecting sensitive health information. While [greater access to real-time patient data](#) has its benefits, it cannot be implemented [without considering risks](#), including security breaches.

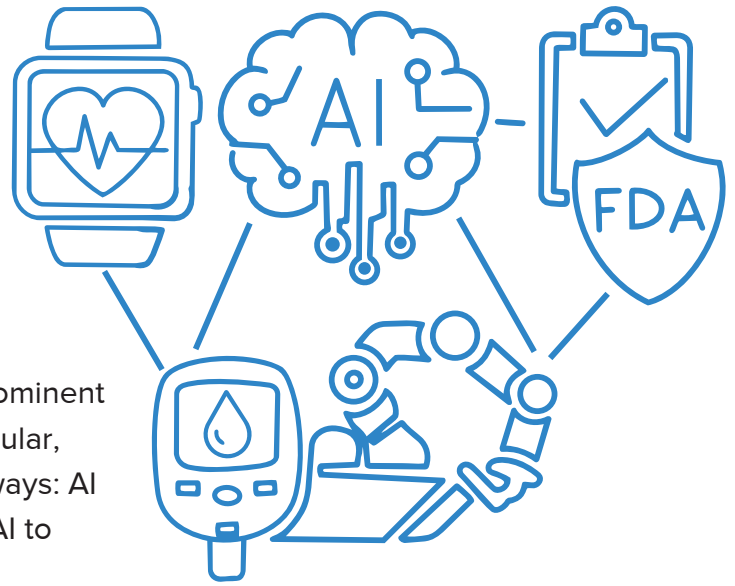


In response to this growing risk, the FDA has [issued new guidance](#) on ensuring cybersecurity in medical devices prior to marketing the device. Adhering to this guidance is essential for companies developing connected health technologies, helping ensure that sensitive patient identifying information and patient health information is kept secure.

TREND 3

Continued Growth of AI-enabled Medical Devices

As artificial Intelligence (AI) continues to become more prominent across the life sciences and healthcare industries in particular, medical device companies are applying it in two distinct ways: AI within the business for internal operations and R&D, and AI to power products that directly impact patient care.

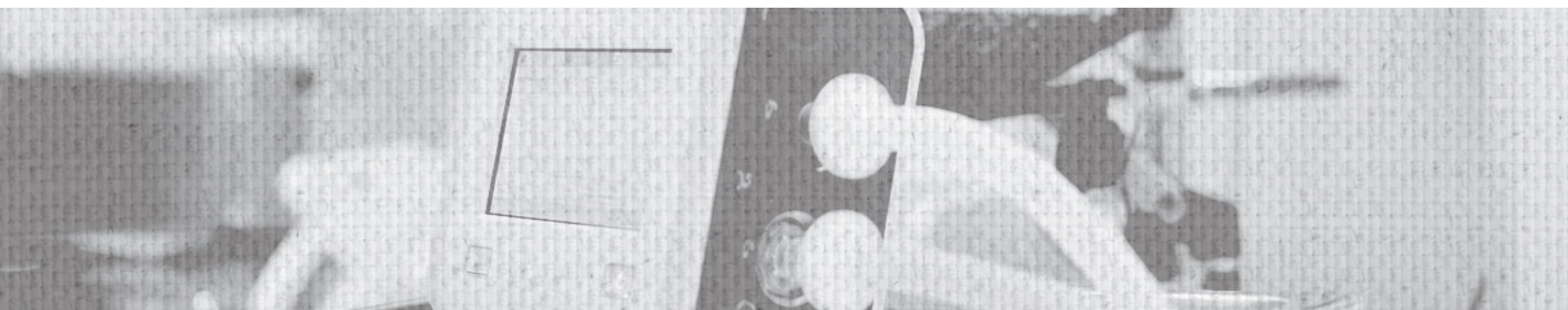


As the landscape of available data continues to increase, medical device companies are finding unique applications of AI to accelerate R&D and support quality and compliance. For example, Johnson & Johnson is leveraging AI to simulate and test their [surgical robotics](#), improving performance and reliability before deployment. However, realizing these benefits depends on a strong data foundation that enables reliable analysis and [organizational adoption](#), ensuring those AI insights can be trusted and acted upon.

At the same time, the number of [AI-enabled medical devices continues to increase](#), especially in devices that continuously collect, store, and transform data. Devices such as ECG-enabled watches rely on AI to analyze signals and detect and report patterns in near real time. In cases like this, AI is enabling automated data analysis and insights and influencing clinical information/patient outcomes. As a result, the bar has been raised for greater validation and oversight of these devices.

Recognizing that need for greater regulatory guidance, the FDA recently [published final guidance](#) for devices with [AI-enabled software](#), acknowledging the challenges and impacts of AI on the total product lifecycle (including validating software) and seeking feedback to develop additional guidance on [measuring device performance](#).

As AI technologies continue to advance and the field rapidly changes, medical device companies must continuously engage with the FDA to stay aligned with emerging guidance and ensure compliance. They'll also need to be prepared to adapt as regulatory expectations continue to evolve.



TREND 4

Tariffs Impacting Pricing and Medical Device Supply Chains

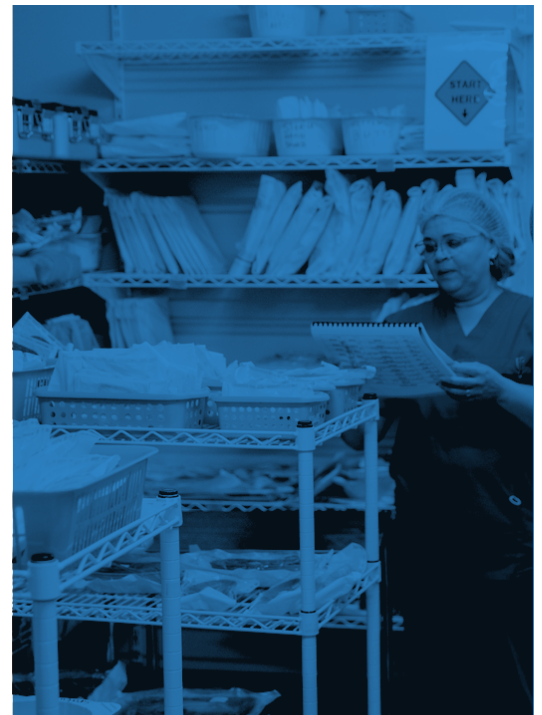


Healthcare prices have increased in all facets, affecting insurance prices, treatments, and medical devices alike. As millions of Americans face [increasing healthcare prices](#), some patients may turn to self-monitoring devices to better understand and manage their health outside of traditional care settings. At the same time, broader economic forces are adding new challenges that could further strain access and affordability for [medical device supply chains](#).

[Tariffs introduce an additional layer of uncertainty](#) for American patients and providers by driving up costs and increasing the risk of supply chain disruption. Many medical devices rely on semiconductors and other globally sourced components, making them particularly vulnerable to tariffs and related shortages. Disruptions could have direct consequences for patient care, affecting everything from [wearable monitoring devices to pacemakers and medical imaging equipment](#).



Hospitals are also exposed to these pressures, [with over \\$75 billion in medical supplies imported in 2024](#). Tariffs on these essential supplies may result in [cost increases, delayed availability, or both](#). Smaller and regional hospital systems are especially at risk, as they often have less flexibility to absorb price increases or source alternatives. These pressures are likely to reach patients who will see [higher out-of-pocket costs or constraints on quality and timeliness of care](#).



In response, medical device companies should take a more proactive approach to supply chain resilience, as tariffs, geopolitical tensions, and [natural disasters](#) remain ongoing realities. By reevaluating sourcing strategies and identifying areas of opportunities – such as using [onshore suppliers](#) or leveraging advanced technologies like [Network Design Optimization](#) and [digital twins](#) – companies can better anticipate disruptions and strengthen their capabilities to deliver devices during times of uncertainty.

Looking Ahead

Medical devices companies continue to embrace digital technologies, allowing patients and healthcare providers to make informed decisions regarding patient care. Continuous monitoring and AI-driven insights are giving patients and providers greater visibility into health trends and potential risks, helping shift care beyond isolated clinical encounters.

As these technologies become more embedded in everyday care, the responsibility to balance innovation with trust grows. Staying aligned with evolving regulatory expectations, and treating data security and patient safety as foundational requirements rather than afterthoughts, will be critical as companies continue to bring new, connected devices to market.

Consider engaging with our [quality and compliance experts](#) to navigate changes in regulatory requirements.

ABOUT CLARKSTON CONSULTING

Businesses across the life sciences industry partner with Clarkston Consulting to enhance strategic decision-making, improve operational efficiencies, implement new technologies, and promote business growth and market diversification. Leveraging deep functional and industry expertise, our people discover, design, and deliver solutions that fit your business, your goals, and your future. At Clarkston, your purpose is our purpose.

For more information about how we can help your company, [please contact us](#).

