



The Medical Device Launch Playbook: Patents, FDA, Reimbursement and Strategic Timing

BY JACEK WNUK, CLAIRE DAVIES,
STEVE STRANNE, M.D. AND EMILY KARR

Polsinelli provides this material for informational purposes only. This material is not intended for use as legal advice. Please consult with a lawyer to evaluate your specific situation. Polsinelli is very proud of the results we obtain for our clients, but you should know that past results do not guarantee future results; that every case is different and must be judged on its own merits; and that the choice of a lawyer is an important decision and should not be based solely upon advertisements.



POLSINELLI®

| What a law firm
should be.®



The Medical Device Launch Playbook

Medical device startups often assume that commercialization is primarily an engineering challenge. In practice, companies often struggle more with integrating the legal, regulatory, reimbursement, and other strategic decisions that determine whether the product can reach — and remain competitive in — the market. Too often, patent filings do not adequately cover the final commercial product, early disclosures impair foreign rights, or changes prompted by Food and Drug Administration (FDA) requirements or reimbursement classifications leave important features unprotected.

Medical device commercialization is therefore most effective when patent, FDA, and reimbursement strategies are developed together in an integrated fashion from the outset, supported by a quality management system, trademarks, financing and commercialization planning. The central objective is to ensure that as the FDA and reimbursement strategies, intended use, and route to market evolve, the patent portfolio and other commercial protections evolve with them.

1. Establish ownership, inventorship, and confidentiality

Before broad disclosure, identify the inventors, document development activity, and determine whether founders, consultants, universities, clinicians, or prior employers have ownership claims. Founders should assign pre-formation intellectual property, and employees and contractors should sign appropriate invention-assignment and confidentiality agreements.

Not every investor will agree to sign confidentiality agreements. Filing before investor outreach and using a nonconfidential presentation can prevent a public disclosure that could forfeit foreign patent rights even when a limited U.S. grace period remains available.

2. Company formation and centralization of IP and regulatory assets

The operating company should own — or hold clear, durable, transferable, and financeable rights to — the patents, know-how, regulatory work product, contracts, software, and data needed to commercialize the device. Entity formation should occur early enough to document those rights and, where relevant, founder vesting, capitalization, securities-law compliance and governance.

3. Clear and protect the brand through trademarks early

Trademark clearance for the company name, house mark, and likely product name should occur before significant investment in branding, packaging, websites or launch materials. Even if a mark has not yet been used in commerce, the company may still file an intent-to-use trademark application.

For many medical device companies, the trademark filing often occurs relatively early in development — after the company has identified likely long-term branding for the business or device, but before substantial investment in packaging, marketing materials, websites, investor presentations, or launch preparation. Medical device companies should consider their target indications for use and evidence generation plans when making branding decisions to avoid branding that could imply unsupported clinical claims or comparative claims, or intended uses outside the scope of their future FDA marketing authorization.¹

4. Evaluate the likely FDA pathway before the patent strategy hardens

Early in development, the company should assess whether the product will be regulated as a medical device and whether it may qualify as a combination product. The company should then evaluate the FDA pathway most likely to apply. This analysis is often iterative, particularly for software-enabled products, including AI-enabled tools; diagnostics; or products that may implicate the drug/biologic and device regulatory frameworks.

If the product is regulated as a medical device, there are four primary regulatory pathways to market.

Many types of devices are exempt from FDA premarket review, so companies should consider whether a new device falls within the scope of an existing exemption, which would allow the device to proceed to market without an FDA submission. It is important to conduct these evaluations carefully and be mindful of device changes that could exceed the limits of the exempt category.

A 510(k) submission to FDA is the pathway to market for many Class II devices and some Class I devices. Clearance depends on demonstrating substantial equivalence to a predicate device. The 510(k) pathway often offers the fastest and most predictable route where an appropriate predicate exists but can constrain product differentiation.

A De Novo request may be submitted for novel low- or moderate-risk devices that lack a predicate. Authorization requires a demonstration that newly developed “special controls” for the novel device type, along with general controls applicable to medical devices broadly, will provide a reasonable assurance of safety and effectiveness. The De Novo pathway typically involves a longer timeline and carries greater uncertainty, but this pathway can also create first-mover advantages if the device later becomes the reference point for the category.

A more stringent Pre-Market Approval Application (PMA) is generally required for higher-risk Class III devices. Approval depends on providing valid scientific evidence, often including clinical data, demonstrating reasonable assurance of the device’s safety and effectiveness for its intended use. The PMA pathway typically involves the longest timeline and heaviest evidence burden but can also support a more durable competitive moat if paired with a well-timed and well-scoped patent portfolio.

If the device is part of a combination product, the company should evaluate “its primary mode of action,” which typically determines which FDA center (drug, device, or biologic) will lead the product’s review and regulation as well as the applicable pathway to market, although specialized regulatory requirements may also apply. Combination products are often the most complex types of FDA-regulated products to bring to market, as novel regulatory issues may require input from multiple FDA centers to resolve.

The anticipated pathway should shape not only the company’s regulatory plan, but also its patent strategy, testing roadmap, financing timeline, and commercialization expectations. Reimbursement strategy and coding considerations may also influence product design, indications for use, evidence generation, and commercialization planning. Patent filings should address not only the initial product concept, but also for foreseeable variants that may be driven by FDA feedback, testing, verification and validation, manufacturing, reimbursement considerations or evolving market positioning.

5. Integrate and reassess FDA, reimbursement and patent strategies

Securing favorable coding, coverage, and reimbursement policies under both public and private health insurers is critical to the commercial success of innovative medical devices. In many instances, medical devices are candidates for desirable Medicare payment incentives for innovation, such as transitional pass-through status, new technology add-on payment (NTAP) status, and non-opioid treatments classification under the Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act. We often use the word “reimbursement” as a shorthand way to refer to the full scope of coding, coverage, and reimbursement considerations that innovative companies pursue under public and private health insurers.

There are many different stakeholders involved in coding, coverage, and reimbursement policy determinations, including the Centers for Medicare & Medicaid Services (CMS), the Medicare Administrative Contractors, individual state Medicaid programs, the American Medical Association, physician professional societies, other organizations that establish clinical guidelines, Blue Cross Blue Shield organizations, and others private payers.

The strategy used to pursue FDA authorization can have substantial impacts on the likelihood and timing of securing favorable coding, coverage, and reimbursement policies adopted by Medicare and other payers. As one example, before an innovative company asks the FDA to determine that their new technology is “substantially equivalent” to a specific predicate device, careful consideration should be focused on the substantive submission content to the FDA and whether and how such a determination will strengthen or complicate the preferred reimbursement pathway. In some instances, a more complex FDA submission or pathway may be desirable to enhance the odds of securing favorable coding, coverage, or reimbursement.



CMS and other health insurers use different standards and approaches than the FDA when evaluating clinical evidence. In general, the FDA determines whether a new device is “safe and effective” while CMS and other health insurers focus on whether the technology is “reasonable and necessary” for the diagnosis or treatment of an illness or injury. Given the cost and time necessary to generate clinical evidence, careful consideration is often warranted to determine whether clinical research protocols and endpoints can be used to satisfy the FDA, CMS, and the other stakeholders involved in health insurer determinations.

As the FDA, reimbursement, and product design strategies evolve throughout the research and development phase, the company’s patent strategies and filings must also evolve to ensure the patents are best positioned to protect the commercial product that reaches the market.

6. File the first provisional application with the commercial product in mind

A patent application should generally be filed before meaningful public disclosure. Medical device companies can begin the patent process in several ways. A provisional patent application is an informal filing with the United States Patent and Trademark Office (USPTO) that establishes an early priority date, but is not examined and cannot become an issued patent on its own. A non-provisional application is examined by the USPTO and can mature into an issued patent. An international Patent Cooperation Treaty (PCT) patent application preserves the option to file national-stage foreign patent applications for numerous PCT member countries, but does not itself confer patent protection.

Although companies can begin with a nonprovisional or PCT filing, early-stage companies often start with a provisional patent application to secure an early priority date while preserving flexibility as the product evolves throughout product development, FDA pathway analysis, fundraising, testing, and commercial planning. A provisional patent application filing should nevertheless describe the invention and foreseeable variants in sufficient detail to establish possession of the invention and support later claims, including relevant software, connectivity, manufacturing approaches, alternative implementations and use cases.

Companies should also evaluate which features warrant patent protection and which may be better maintained as trade secrets. Manufacturing know-how, process parameters, internal software tools, model weights, data pipelines and supplier information may derive greater long-term value from confidentiality than from public patent disclosure. Revisit that allocation as FDA submissions, reimbursement considerations, manufacturing scale-up, and commercialization clarify what competitors may be able to observe or reverse engineer.



7. Track the major patent deadlines carefully

Foreign-filing authorization, the twelve-month priority period, and PCT national-phase deadlines are principal patent protection timing checkpoints.

For inventions made in the United States, a company generally must obtain a foreign filing license before filing abroad. If no secrecy order has been imposed, that restriction generally expires six months after the U.S. filing, although the USPTO often grants a license earlier.² A company must claim the provisional application's priority within twelve months of the provisional patent application filing date,³ for instance by filing a non-provisional patent application, an international PCT patent application, and/or direct foreign national patent applications (e.g., in non-PCT jurisdictions or if a PCT application is not filed).⁴ If an international PCT patent application is filed, the deadlines to file national-phase patent applications in foreign jurisdictions begin thirty months from the earliest priority date (e.g., provisional application's filing date if one is filed) for PCT member states.⁵

8. Synchronize patent strategy and FDA development

One of the most important strategic points in device commercialization is that FDA development and reimbursement considerations should inform patent strategy, and vice versa. As the device evolves through testing, usability work, verification, validation, human factors analysis, manufacturing scale-up, and FDA feedback, the patent portfolio should evolve as well.⁶

Different FDA pathways can also create different development timelines and strategic pressures, as described above. For example, a traditional 510(k) submission may move relatively quickly if a strong predicate device exists and the technological differences are limited, whereas De Novo requests often involve more uncertainty because the company is effectively helping FDA establish a new classification framework for a novel device type.

FDA interactions also frequently reshape the ultimate commercial product. In many cases, the FDA-facing submission materials become a clear written description of the product the company actually intends to market, which is why they should be reviewed not only by regulatory counsel, but also through the lens of patent portfolio coverage. FDA may request revised labeling, modified indications for use, additional testing, cybersecurity controls, software documentation, or design changes during the review process. Those changes can materially affect which features ultimately matter most from a patent perspective.

Companies thus often benefit from filing continuation patent applications, follow-on provisional patent applications, or additional non-provisional utility filings as the commercial design matures. The closer the company gets to a final FDA-facing product configuration, the more important it becomes to confirm that the patent portfolio meaningfully protects the actual marketed product.

9. Refresh freedom-to-operate analysis before commercialization

Freedom-to-operate (FTO) analysis should not be treated as a one-time exercise performed at the concept stage. It is usually more valuable when revisited as the product approaches its final regulatory and commercial configuration.

This is especially important for products pursuing 510(k) clearance because the final device may intentionally resemble an existing predicate device. In practice, the most meaningful time to revisit freedom-to-operate analysis is often shortly before major FDA submissions, when the product configuration, labeling, software functionality, and intended use have stabilized. At that stage, FTO analysis can inform not only infringement-risk assessment, but also design-around decisions, licensing strategy, and transaction readiness.

10. Consider whether and when to pursue design patent protection

Medical device companies should also consider whether aspects of the product's visual appearance may warrant design patent protection. Unlike utility patents, which protect functional inventions, design patents protect the ornamental appearance of at least a portion of a product, and can even include graphical user interface elements.

Design patent protection turns on the claimed visual appearance, it often makes sense to wait until the design has stabilized but before public disclosure. is close to finalized before filing. If the appearance changes substantially after filing, the design patent may provide less protection than expected; if the filing comes too late, public disclosure or competitor copying may intervene. Filing design patent applications directed at several candidate designs can balance these interests, and may help protect future iterations of a product or likely competitor variants.⁷

11. Build quality systems, cybersecurity and compliance infrastructure during development

A quality management system, including applicable design controls, supplier oversight, cybersecurity planning, complaint-handling systems, and validation documentation should be built and implemented during development—not immediately before launch.⁸

For connected devices and software-enabled products, cybersecurity planning should include secure development practices, vulnerability management, software update planning, postmarket vulnerability monitoring processes, and access-control architecture. FDA's cybersecurity expectations for connected medical devices have also become increasingly formalized, particularly for devices that qualify as "cyber devices" under recent statutory changes and FDA guidance.^{9,10} As a result, cybersecurity considerations should be incorporated into product development from the outset rather than addressed immediately before submission.

12. Engage FDA before expensive decisions become difficult to reverse

If the product classification, evidence strategy, or marketing pathway remains uncertain, companies may benefit from engaging FDA through the Q Pre-Submission process before committing to expensive validation or clinical work. However, FDA's current policies target a 70-day timeframe for providing written feedback on a Pre-Submission, so companies should build that into their development and launch timeframes.

A Pre-Submission can allow the company to obtain FDA feedback on testing protocols, clinical strategy, software documentation, cybersecurity expectations, human factors plans, predicate positioning, or other major regulatory questions before committing significant resources. Such feedback may help streamline product development, reduce regulatory uncertainty, and facilitate a more efficient review process. At this stage, patent counsel should also evaluate whether existing filings adequately cover the FDA-facing product and whether additional filings or continuation strategies are warranted.¹¹

13. Treat the FDA submission and review process as a patent event

By the time the company prepares a 510(k) submission, De Novo request, or PMA, the FDA submission often provides one of the clearest written descriptions of the intended commercial product. That makes the pre-submission period a critical patent checkpoint.

The timing and procedural mechanics of the submission also matter strategically. FDA states that it aims to review most traditional 510(k) submissions within approximately ninety FDA review days, although requests for additional information, and iterative review cycles can extend the timeline substantially.¹² De Novo requests and PMAs often involve even more interaction regarding controls, clinical data and other evidence, labeling, and risk mitigation. As a result, the submission and review process should be treated as an evolving phase of product definition, not merely a waiting period.

Before filing, companies should compare the submission-ready product, labeling, intended use and technical features against the pending patent portfolio. If the product has evolved materially, this may be the appropriate stage for continuation filings, claim adjustments, or additional applications.¹³ Continuations can be used to pursue claims supported by a pending parent application, while material new features may require a new filing.

14. Evaluate patent term extension and lifecycle strategy before approval

Companies pursuing devices subject to PMA or other products subject to lengthy regulatory review should evaluate whether patent term extension opportunities may be available under the Hatch-Waxman framework (35 U.S.C. § 156) applicable to eligible medical devices.¹⁴

Although device-related patent term extensions are used less frequently than pharmaceutical extensions, they can provide meaningful additional exclusivity if planned properly. Lifecycle planning may also include continuation practice, next-generation filings, design patents, software claims, and method-of-use claims intended to extend competitive protection over time.¹⁵

15. Prepare for launch: patent marking, branding alignment and registration

As commercialization approaches, confirm that product branding aligns with both trademark filings and FDA-authorized labeling. Intent-to-use trademark applications will eventually require evidence of qualifying use in commerce before registration.

Commercial launch also introduces additional FDA advertising and promotional considerations. Marketing claims, website language, sales training materials, investor presentations, and reimbursement communications should remain consistent with the device's FDA-cleared or approved indications for use.

Companies should also evaluate patent marking strategy. Proper patent marking under 35 U.S.C. § 287 can strengthen damages positions in future infringement litigation and may influence competitive positioning.¹⁶



16. Launch, lifecycle management and long-term protection

By launch, the company should be able to answer three questions clearly: What product did FDA clear or approve? What product will actually be sold? And what product does the patent portfolio meaningfully protect?

The strongest medical device launch strategies treat patents, FDA planning, reimbursement strategy, commercialization, a quality management system, and lifecycle management as interconnected from the beginning. Patent filings should evolve alongside FDA feedback, testing, usability work, manufacturing realities, commercialization strategy, and post-launch product changes. FDA submissions and review periods should be treated not merely as regulatory hurdles, but also as opportunities to reassess claim coverage, continuation strategy, freedom-to-operate considerations and long-term competitive positioning.

This playbook is a strategic framework rather than a one-size-fits-all roadmap. The appropriate sequencing of patent filings, FDA submissions, quality management system development, clinical work, commercialization planning, and related legal activities will vary depending on the technology, regulatory pathway, financing strategy, target markets and business objectives involved. The authors and other Polsinelli attorneys regularly advise clients across the medical device lifecycle, from early patent strategy and FDA pathway planning through commercialization and portfolio management.

Key Strategic Timeline Milestones

Milestone	Strategic significance
Pre-disclosure	Confirm ownership, confidentiality protections, and inventorship.
Provisional patent application filing date	File provisional patent application before meaningful public disclosure.
Early development	Clear trademarks; evaluate FDA and reimbursement pathways, predicate landscape, product classification, patentability, an FTO.
Before any foreign filing	Confirm a foreign filing license or the six-month/no-secrecy-order basis for filing; finalize international filing instructions.
During development	Build QMS, cybersecurity, design controls, and refreshed FTO analysis.
Before major testing	Consider FDA Q-Submission engagement, including Pre-Submissions.
12 mo. after provisional application filing	File nonprovisional application, international PCT application and national-stage foreign filings for non-PCT countries.
FDA submission stage	Align the patent portfolio with the FDA-facing product and labeling and the anticipated reimbursement strategy.
FDA review period	Respond to deficiency letters or requests for additional information, and reassess patent claim coverage as the FDA-facing product and labeling and reimbursement strategies continue to evolve.
30 mo. after provisional application filing	File national-stage foreign filings for PCT member countries.
Post-clearance / approval	Complete trademark use filings as applicable, and patent marking implementation.
Post-launch	Evaluate continuation practice, pursue coding, coverage, and reimbursement strategies, portfolio expansion, enforcement and potential patent term extension opportunities.

Endnotes

- 1 USPTO, "Trademark applications – intent-to-use (ITU) basis," <https://www.uspto.gov/trademarks/apply/intent-use-itu-applications>
- 2 USPTO, MPEP § 140: "Foreign Filing Licenses," <https://www.uspto.gov/web/offices/pac/mpep/s140.html>
- 3 USPTO, "Provisional Application for Patent," <https://www.uspto.gov/patents/basics/apply/provisional-application>
- 4 WIPO, "States bound by the Paris Convention but not the PCT," https://www.wipo.int/en/web/pct-system/paris_non_pct; Taiwan Intellectual Property Office, "Can I apply a PCT international application in the ROC?" <https://www.tipo.gov.tw/en/tipo2/391-2548.html>
- 5 WIPO, "Time Limits for Entering National/Regional Phase under PCT Chapters I and II (in months from priority date)," https://www.wipo.int/en/web/pct-system/texts/time_limits
- 6 FDA, "Applying Human Factors and Usability Engineering to Medical Devices," <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>
- 7 USPTO, "Design patent application guide," <https://www.uspto.gov/patents/basics/apply/design-patent>
- 8 FDA, "Quality Management System Regulation (QMSR)," <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
- 9 FDA, "Cybersecurity in Medical Devices Frequently Asked Questions (FAQs)," <https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity-medical-devices-frequently-asked-questions-faqs>
- 10 FDA, "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions" Guidance (February 2026), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket>.
- 11 FDA, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" Guidance (May 2025), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>
- 12 FDA, "510(k) Submission Process," <https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-process>
- 13 FDA, "PMA Review Process," <https://www.fda.gov/medical-devices/premarket-approval-pma/pma-review-process>
- 14 USPTO, "35 U.S.C. § 156 Extension of patent term," <https://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#d0e303884>
- 15 USPTO, "Patent Term Extension and Adjustment," <https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156>
- 16 USPTO, "Managing a patent," <https://www.uspto.gov/patents/basics/manage>



Jacek Wnuk
Principal



Claire Davies
Shareholder



Steve Stranne, M.D.
Shareholder

Contributor: Emily Karr, 2026 Summer Associate



POLSINELLI | What a law firm
should be.™

polsinelli.com | Polsinelli is very proud of the results we obtain for our clients, but you should know that past results do not guarantee future results; that every case is different and must be judged on its own merits; and that the choice of a lawyer is an important decision and should not be based solely upon advertisements. Copyright © 2026 Polsinelli PC. Polsinelli LLP in California, Polsinelli PC (Inc) in Florida.