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NextGenMedTech

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A TECHNICAL GUIDE TO

U.S. FDA 510(k) SUBMISSIONS

2026 Edition

CHAPTER 1

The 510(k) Pathway — Legal Basis, Scope & Strategic Context

Prepared for Medical Device Manufacturers, Regulatory Affairs Professionals, and Innovation-Driven MedTech Teams Preparing for U.S. Market Entry

Current as of April 2026 | Based on FDA CDRH Guidance

Chapter 1: The 510(k) Pathway — Legal Basis, Scope & Strategic Context

The U.S. Food and Drug Administration's 510(k) premarket notification process is the primary regulatory gateway through which most medical devices reach the American market. Understanding its legal foundations, strategic scope, and operational mechanics is not merely academic — it is a prerequisite for any manufacturer, regulatory affairs professional, or innovator intending to commercialize a medical device in the United States. This chapter establishes the foundational framework upon which every subsequent chapter in this guide is built.

From its origins in the Medical Device Amendments of 1976 to the complex, digitized submission environment of 2026, the 510(k) pathway has evolved considerably — yet its core premise remains unchanged: a device may be marketed in the U.S. without a full clinical trial program, provided the submitter can demonstrate to FDA's satisfaction that the device is substantially equivalent to a legally marketed predicate device. This principle — at once elegant and demanding — defines the strategic landscape for every 510(k) submission.

1.1 History and Statutory Authority

1.1.1 Origins: The Medical Device Amendments of 1976

Prior to 1976, the United States had no comprehensive framework for regulating medical devices as a distinct product category. Devices were regulated sporadically under the broader provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938, primarily through misbranding and adulteration provisions that were ill-suited to the technical realities of medical hardware and diagnostic instruments. A series of public health failures in the late 1960s and early 1970s — most notably the Dalkon Shield intrauterine device, which caused severe harm to thousands of women — catalyzed congressional action.

The Medical Device Amendments of 1976 (Pub. L. 94-295) represented a landmark legislative achievement. Signed into law by President Ford on May 28, 1976, the Amendments created the foundational architecture for modern medical device regulation in the United States. They established a tiered classification system based on risk, created distinct regulatory pathways for different device classes, and granted the FDA authority to require premarket review for higher-risk devices. Crucially, they also introduced the 510(k) premarket notification

mechanism under Section 510(k) of the FD&C Act — a provision that would prove to be the most-used regulatory pathway in the history of medical device oversight.

The 510(k) number itself derives directly from the section of the FD&C Act that established the requirement. Any person intending to introduce a device into interstate commerce must notify the FDA at least 90 days before doing so, if that device was not in commercial distribution before May 28, 1976 (the "preamendment" date). This notification — the 510(k) submission — initiates the review process through which FDA determines whether the new device is substantially equivalent to a predicate.

1.1.2 Key Legislation and Regulatory Milestones

The 1976 Amendments were not the last word on device regulation. A succession of laws have refined, expanded, and modernized the 510(k) framework:

Year	Legislation / Action	Impact on 510(k)
1976	Medical Device Amendments	Created the 510(k) pathway, device classification system (Class I/II/III), and substantial equivalence standard.
1990	Safe Medical Devices Act (SMDA)	Strengthened postmarket surveillance requirements; enhanced FDA authority to require performance standards.
1997	Food and Drug Administration Modernization Act (FDAMA)	Introduced the Abbreviated 510(k) pathway; enabled use of recognized consensus standards; created third-party review program.
2002	Medical Device User Fee and Modernization Act (MDUFMA)	Established user fees for 510(k) submissions; set performance goals for FDA review timelines.
2012	FDA Safety and Innovation Act (FDASIA)	Strengthened CDRH oversight; directed FDA to issue guidance on 510(k) program improvements.
2016	21st Century Cures Act	Supported digital health and software as a Medical Device (SaMD) provisions; encouraged breakthrough device designation.
2022	FDA Omnibus Reform Act (FORA)	Introduced new cybersecurity requirements (Section 524B) for "cyber devices"; now fully in effect.

2026	QMSR (Final Rule, eff. Feb. 2)	Replaced QSR with ISO 13485-aligned Quality Management System Regulation, reshaping quality documentation in submissions.

1.1.3 The Governing Regulation: 21 CFR Part 807 Subpart E

The implementing regulation for 510(k) submissions is found at Title 21 of the Code of Federal Regulations (21 CFR), Part 807, Subpart E. This subpart — covering sections 807.81 through 807.100 — establishes the mandatory requirements for when a 510(k) must be submitted (§807.81), what the submission must contain (§807.87), and the special provisions applicable to contact lens solutions and other specific device categories (§807.92–807.97).

Section 807.87 is the practitioner's primary reference. It enumerates the required elements of a premarket notification, including the device name, establishment registration number, device classification, performance standards, intended use statement, comparison to predicate devices, and performance data. Compliance with §807.87 forms the backbone of every section in this guide.

FDA's implementing guidance — most notably "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" — provides the operational interpretation of these statutory and regulatory requirements. This guidance, along with a constellation of device-specific and topic-specific guidances issued by CDRH, shapes how submissions are prepared and reviewed in practice.

1.2 The Three Submission Types: Traditional, Abbreviated, and Special 510(k)

Within the 510(k) framework, FDA recognizes three distinct submission types, each suited to different scenarios. Selecting the appropriate type is an early strategic decision with consequences for submission structure, the type of supporting data required, and the overall complexity of the application.

1.2.1 The Traditional 510(k)

The Traditional 510(k) is the standard, comprehensive submission pathway. It requires the submitter to provide all information necessary to support a determination of substantial equivalence, including a full device description, intended use statement, comparison to a named predicate device, and all performance data — bench, biocompatibility, software, clinical, and other testing as applicable.

The Traditional 510(k) is the default pathway when neither the Abbreviated nor the Special pathway criteria are met. It is also the appropriate choice when no applicable FDA-recognized consensus standard or device-specific guidance document covers the full scope of the new device's intended use and technological characteristics. For novel devices or devices with significant technological differences from their predicate, the Traditional pathway is almost always required.

Traditional 510(k) submissions tend to be the most resource-intensive, but they offer the greatest flexibility in how substantial equivalence is argued and supported. There is no prescribed format for the performance testing section, for instance — the submitter constructs the evidentiary package appropriate to the device and its risk profile.

1.2.2 The Abbreviated 510(k)

Introduced under FDAMA 1997 and governed by FDA's guidance on the Abbreviated 510(k) program, this pathway allows manufacturers to streamline the performance data section of their submission by relying on one or more of the following:

- FDA-recognized consensus standards (e.g., ISO, ASTM, IEC standards listed in FDA's Standards Database)
- FDA guidance documents that define the scientific and technical requirements for a specific device type
- Special controls established for a device classification under 21 CFR

Rather than providing the full test data in the submission itself, the Abbreviated 510(k) submitter can provide a declaration of conformity to the relevant standard or guidance, supported by summary reports demonstrating compliance. This can significantly reduce the volume of documentation in the submission, but it does not reduce the underlying testing burden — all testing must still be performed; the submission simply presents it in a more condensed format.

It is a common misconception that the Abbreviated pathway is always easier or faster. In many cases, demonstrating full conformity to a consensus standard is as demanding as providing the full test data. The Abbreviated 510(k) is most advantageous when an applicable standard exists, the device design closely conforms to that standard, and the testing has already been completed to meet international market requirements.

1.2.3 The Special 510(k)

The Special 510(k) pathway is available only to manufacturers who are modifying their own previously cleared device. It is not available for new entrants or for modifications to a

competitor's device. The rationale is that the manufacturer already has an established relationship with FDA, a cleared device on record, and a functioning Design Control process under which the modification was developed.

The Special 510(k) is particularly well-suited to:

- Minor design modifications that do not change the intended use
- Changes to materials, dimensions, or processing methods within validated parameters
- Software updates that do not alter the fundamental operating principle of the device

The submission relies heavily on the manufacturer's own Design Control documentation — design verification and validation (V&V) summaries — rather than complete new performance testing. FDA's review of a Special 510(k) is typically faster, with a target review time of 30 days. However, FDA may convert a Special 510(k) to a Traditional 510(k) if the reviewer determines that the changes are more substantial than represented.

The decision framework for when a device change requires a new 510(k) (versus a design change that can be managed internally) is governed by FDA's guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" and is addressed in detail in Chapter 15 of this guide.

Practical Tip: Choosing Your Submission Type

Begin your submission strategy by asking three questions: (1) Does FDA have a recognized standard or guidance document that covers all key aspects of my device? If yes, consider Abbreviated. (2) Am I modifying my own cleared device, and is the change confined to design, not intended use? If yes, consider Special. (3) Neither of the above? Default to Traditional. When in doubt, the Pre-Submission (Q-Sub) program (covered in Chapter 13) provides an opportunity to confirm your pathway choice with the relevant FDA reviewer before committing resources.

1.3 510(k) vs. De Novo vs. PMA — Choosing the Right Pathway

Understanding the 510(k) pathway in isolation is insufficient. A sophisticated regulatory strategy requires a clear understanding of when the 510(k) is the appropriate pathway, and when De Novo or Premarket Approval (PMA) should be considered instead. Making the wrong pathway choice at the outset can result in months or years of lost time.

1.3.1 The Premarket Approval (PMA) Pathway

PMA is the most stringent device regulatory pathway and is required for Class III devices — those for which substantial equivalence to a predicate cannot be established and for which general and special controls alone are insufficient to provide reasonable assurance of safety and effectiveness. PMA requires independent, valid scientific evidence — typically including randomized controlled clinical trials — to demonstrate safety and effectiveness.

PMA applications are substantially more resource-intensive than 510(k) submissions: they typically take two to four years to prepare, cost millions of dollars in testing and clinical study expenses, and require an average FDA review time of 180 days (with typical total timelines of 12–24 months including supplemental interactions). Examples of PMA devices include implantable cardioverter defibrillators, cochlear implants, and high-risk in vitro diagnostic assays for life-threatening conditions.

The 510(k) pathway becomes unavailable for PMA-class devices once FDA determines that a device has no valid predicate and that the risks it presents are not adequately addressed by general and special controls alone. For innovators developing breakthrough technologies in previously unaddressed indications, PMA may be the mandatory path.

1.3.2 The De Novo Classification Request

De Novo is the regulatory pathway for novel, low-to-moderate-risk devices that have no valid predicate — and therefore cannot be cleared through the 510(k) process — but do not pose the degree of risk that would warrant PMA. De Novo was created by FDAMA 1997 and significantly expanded by the 21st Century Cures Act (2016). It is, in essence, a petition for the FDA to create a new device classification, complete with special controls, into which the requesting device (and future similar devices) can be placed.

A successful De Novo creates a new classified device type. The device that received De Novo authorization then becomes available as a predicate for future 510(k) submitters. This is a critical structural feature of the U.S. regulatory system: De Novo does not simply clear a single device — it establishes the legal and scientific framework for an entire product category.

De Novo requests are appropriate when a manufacturer can demonstrate that its device is low-to-moderate risk and can be adequately controlled through specific performance standards and labeling requirements (special controls), but cannot point to a legally marketed predicate with the same intended use. The pathway typically takes 12–18 months and requires detailed performance testing, risk analysis, and proposed special controls.

1.3.3 Pathway Comparison Matrix

Feature	510(k)	De Novo	PMA
Device Risk Class	Class I / II	New Class I or II	Class III
Predicate Required?	Yes	No	No
Clinical Trial Required?	Rarely	Sometimes	Usually
Avg. FDA Review Time	~90 days	12–18 months	180 days (review only)
Total Timeline	6–18 months	18–30 months	3–7 years
Cost (Approx.)	$50K–$500K+	$300K–$2M+	$5M–$50M+
Creates New Predicate?	No	Yes	No
User Fee (FY2025)	$24,335 / $6,084*	$23,080 / $5,770*	$526,186 / $131,547*

**Standard fee / Small Business fee. Fees updated annually October 1.*

1.3.4 Strategic Pathway Selection Considerations

The choice of regulatory pathway is one of the highest-stakes decisions in a medical device company's regulatory strategy. A number of factors should be systematically evaluated:

1. Predicate availability: Can you identify a legally marketed device with the same intended use? If not, 510(k) is unavailable. Consider De Novo if risk is moderate or PMA if high.
2. Risk profile: What is the potential harm to patients if the device malfunctions? Higher risk generally implies a higher regulatory bar and may shift the pathway to PMA regardless of predicate availability.
3. Speed-to-market: 510(k) offers the fastest route if a strong predicate exists. PMA is the slowest. De Novo is intermediate.
4. Competitive dynamics: De Novo creates a new classification that competitors can then use as a 510(k) predicate. If establishing a market-defining standard is strategically valuable, this can outweigh the longer timeline.
5. Breakthrough Device Designation: For devices addressing life-threatening or irreversibly debilitating conditions, Breakthrough Device Designation (available for all three pathways) can accelerate FDA review through dedicated reviewer interaction, priority review, and rolling submissions.

1.4 The Device Classification System: Class I, II, III and Product Codes

Central to every 510(k) strategy is an accurate determination of the subject device's regulatory classification. FDA's classification system assigns medical devices to one of three classes based on their risk profile and the regulatory controls necessary to provide reasonable assurance of safety and effectiveness.

1.4.1 Class I Devices — General Controls

Class I devices are considered the lowest-risk category. They are subject to general controls under Section 501, 502, 510, 516, 518, 519, and 520 of the FD&C Act — including establishment registration, device listing, Quality Management System requirements, labeling requirements, Medical Device Reporting (MDR), and prohibition against adulteration and misbranding. The vast majority of Class I devices are exempt from 510(k) requirements, meaning they do not need premarket notification before marketing, provided they remain within the limitations of the applicable exemption (found in the .9 section of each device classification regulation).

Examples of Class I devices include: elastic bandages, examination gloves, handheld surgical instruments, and manual stethoscopes. While Class I devices are generally low-risk, exemption is not a universal rule — some Class I devices are not 510(k)-exempt and do require a premarket notification. Verification of exemption status in the FDA Product Classification Database is always required before assuming a 510(k) is unnecessary.

1.4.2 Class II Devices — Special Controls

Class II represents the heart of the 510(k) landscape. These are moderate-risk devices for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness, but for which sufficient information exists to establish special controls — such as performance standards, postmarket surveillance requirements, patient registries, special labeling requirements, and guidelines — that, together with general controls, can provide such assurance.

The overwhelming majority of 510(k) submissions — and virtually all cleared 510(k)s — involve Class II devices. Examples span an enormous range: diagnostic imaging equipment, powered wheelchairs, infusion pumps, contact lenses, glucose monitors, ECG machines, and tens of thousands of other device types. FDA's product codes for Class II devices number in the thousands.

1.4.3 Class III Devices — Premarket Approval

Class III devices are the highest-risk category, representing devices that support or sustain human life, are substantially important in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. These devices generally require PMA unless they have a legally marketed predicate from before 1976 (preamendment devices) or have been reclassified to a lower class through a rulemaking process.

Some Class III devices do have 510(k) predicates — particularly those that entered the market before the PMA requirement was fully implemented or that were cleared under predecessor classification schemes. However, FDA has been progressively tightening the availability of Class III 510(k) clearances. A manufacturer who identifies a Class III predicate should carefully evaluate whether FDA has since required PMA for that device type, as the regulatory landscape in this space has evolved substantially.

1.4.4 The FDA Product Classification Database and Product Codes

Every FDA-regulated device is assigned a three-letter product code that identifies its specific device type within the classification system. These codes, managed by CDRH's Product Classification database (accessible at fda.gov), are the regulatory DNA of every device and determine:

- The device's classification (Class I, II, or III)
- The applicable regulation number (e.g., 21 CFR 880.5860 for a particular monitoring device)
- Whether the device is 510(k)-exempt
- Any applicable special controls or recognized performance standards
- The review panel responsible for evaluating submissions in that product category

Correctly identifying the product code for a new device is not always straightforward. A single product can potentially be classified under multiple product codes depending on its intended use, technology, and the specific claims being made. Where ambiguity exists, a 513(g) Request for Information to FDA (a formal pathway to obtain the agency's classification opinion) or a Pre-Submission meeting can resolve the question before a 510(k) is filed. Misclassification is a significant source of RTA deficiencies and substantive review delays.

Key Regulatory Reference: Finding Product Codes

The FDA's Product Classification database is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm. Search by device name, regulation number, or product code. The 510(k) database (accessible at the same portal)

allows you to search cleared devices by product code, providing a searchable repository of potential predicates.

1.5 Who Must Submit — Domestic Manufacturers, Importers, Repackagers, and Contract Manufacturers

One of the most practically important, and frequently misunderstood, aspects of the 510(k) requirement is determining which parties are legally required to submit. The FD&C Act and 21 CFR Part 807 define this obligation by reference to the action being taken — introducing a device to interstate commerce — rather than the identity of the party.

1.5.1 Domestic Manufacturers

A domestic manufacturer who introduces a device to the U.S. market under their own specification is the paradigm case for 510(k) submission obligation. This encompasses finished device manufacturers — companies that design, manufacture, and market devices under their own name and specifications. Accessories intended to be sold to end users are treated as finished devices for 510(k) purposes; manufacturers of components sold to other manufacturers for incorporation into a finished device, however, are generally not required to submit.

1.5.2 Importers

Foreign-manufactured devices imported into the U.S. require a 510(k) submitted by the U.S. importer, the foreign manufacturer, or their authorized representative. The importer of record bears primary responsibility for ensuring that a valid clearance exists for the device before it enters U.S. commerce. It is not sufficient to rely on regulatory approvals from other jurisdictions (CE marking, PMDA approval, TGA clearance) as a substitute for 510(k) clearance — these are independent regulatory determinations under different legal standards.

1.5.3 Repackagers and Relabelers

A repackager or relabeler who significantly changes the labeling of a device or repackages it in a manner that affects safety (e.g., changing sterility assurances, altering indications) may need to submit their own 510(k). Minor repackaging — for example, adding a "distributed by" label without changing any specifications, indications, or warnings — generally does not

require a new 510(k). The legal standard is whether the repackaging or relabeling constitutes a "significant change" to the device as defined by 21 CFR 807.81(a)(3).

1.5.4 Contract Manufacturers

Contract manufacturers — firms that manufacture a device to another company's specifications under contract — are generally not required to submit a 510(k), because they do not introduce the device into commerce on their own behalf. The specification holder (the company whose design is being manufactured) is the party responsible for the 510(k). This distinction is important in complex supply chains where manufacturing may be outsourced while regulatory ownership resides with the design firm.

1.5.5 Exempt Categories

Several categories of devices are exempt from 510(k) requirements and do not require premarket notification even if they are being introduced to the U.S. market for the first time:

- Class I devices that are listed as 510(k)-exempt in their applicable classification regulation (and do not exceed the limitations of the exemption)
- Devices that were legally in commercial distribution before May 28, 1976 (preamendment devices) and have not been significantly changed or modified
- Custom devices manufactured for a named patient under the custom device exemption of Section 520(b)
- Certain humanitarian use devices under the HDE pathway
- Devices approved under PMA (which have their own change supplement requirements, not 510(k))

Determination of exempt status must be made affirmatively — it is not safe to assume exemption without consulting the relevant classification regulation and the FDA's current exemption determinations for the specific product code. Changes to an exempt device can lift the exemption and require a 510(k) submission.

1.6 Current Submission Volumes and the 2026 Review Environment

Contextualizing the current 510(k) landscape requires understanding both the scale of the program and the specific environmental factors shaping submission strategy in 2026.

1.6.1 Volume and Clearance Statistics

The 510(k) program handles an enormous volume of activity. In recent fiscal years, FDA has received and acted upon more than 3,000 clearance decisions annually — approximately 3,326 clearances in FY2023, 3,107 in FY2024, and 3,238 in FY2025. Total submissions (including those that are withdrawn or not cleared) number in the range of 4,500 to 5,000 per year. To put this in operational terms, CDRH must render approximately 15 clearance decisions per business day simply to keep pace with incoming submissions.

This throughput reality has significant implications for submission quality. Reviewers are working under time pressure, and a submission that requires extensive clarification or generates numerous Additional Information (AI) requests consumes disproportionate reviewer resources. High-quality, complete, and clearly organized submissions are not merely good practice — they are, structurally, the most effective way to achieve timely clearance.

1.6.2 The 2026 Regulatory Environment

The 510(k) review environment in 2026 is characterized by several intersecting dynamics that every submitter must understand:

FDA Workforce Dynamics: CDRH has navigated significant organizational change in 2025, including workforce reductions across the broader agency and leadership transitions. While many device reviewers were subsequently restored, reviewer bandwidth remains stretched and administrative support functions have been reduced. This has created longer average response times for informal reviewer guidance and Q-Sub feedback. The implication for submitters is clear: formal, documented interactions through official channels (Q-Subs, written responses) are more important than ever. Submissions that rely on informal pre-submission alignment with reviewers carry greater risk in the current environment.

Increased Scrutiny of Submissions: In the context of stretched resources, FDA reviewers are increasingly reliant on well-prepared, self-evidently complete submissions. There is reduced capacity for the reviewer to seek out information that should have been in the submission. Incomplete submissions are more likely to generate RTA findings or substantive information requests that add months to the clearance timeline. The 2026 environment rewards meticulous pre-submission preparation.

Deregulatory Signals in Digital Health: Under Commissioner Makary, FDA has signaled a shift in regulatory philosophy in certain areas — particularly digital health. The January 2026 revised guidance on Clinical Decision Support (CDS) software significantly narrowed the

scope of software regulated as a medical device, with an enforcement discretion policy for certain CDS functions. Manufacturers of software products should carefully assess whether their device is still subject to 510(k) requirements under the updated framework.

QMSR Transition: The Quality Management System Regulation (QMSR), effective February 2, 2026, replaces the decades-old Quality System Regulation (QSR) with an ISO 13485:2016-aligned framework. This is the most significant change to the U.S. device quality system requirements in 30 years. Its implications for 510(k) submissions — particularly the design control documentation and verification/validation evidence included in or referenced by the submission — are addressed in detail in Chapter 12.

1.7 Chapter Summary and What Lies Ahead

This chapter has established the legal and strategic foundations of the 510(k) pathway. The key principles to carry forward through the remainder of this guide are:

- The 510(k) is a premarket notification, not a premarket approval. The legal standard is substantial equivalence — not independent proof of safety and effectiveness.
- Three submission types exist (Traditional, Abbreviated, Special), each suited to different scenarios. Selection of the appropriate type is an early strategic decision.
- The 510(k) exists within a broader pathway ecosystem (De Novo, PMA) and the choice between them is consequential. Pathway misidentification is costly.
- Correct device classification and product code identification are prerequisites for every submission and directly determine the regulatory requirements that apply.
- The obligation to submit is tied to the action (introducing a device to commerce) not just the manufacturer's identity — importers, repackagers, and relabelers may also be required to submit.
- The 2026 regulatory environment rewards exceptionally well-prepared, complete submissions. Informality, ambiguity, and incomplete documentation are more costly than ever.

Chapter 2 moves from these foundations to one of the most consequential decisions in any 510(k) strategy: the selection of the predicate device. As subsequent chapters will demonstrate, the predicate is not merely a regulatory formality — it is the scientific, legal, and strategic anchor upon which the entire substantial equivalence argument is built. Getting predicate selection right is the single most impactful thing a regulatory team can do to improve the probability of a timely, successful clearance.

Key Terms and Definitions

Term	Definition
510(k)	A premarket notification submitted to FDA under Section 510(k) of the FD&C Act to demonstrate that a new device is substantially equivalent to a legally marketed predicate device.
Predicate Device	A legally marketed device to which substantial equivalence is claimed. Must share the same intended use as the subject device.
Substantial Equivalence (SE)	The legal standard for 510(k) clearance: the new device has the same intended use as the predicate and either the same technological characteristics, or different technological characteristics that do not raise new safety/effectiveness questions and the device is at least as safe and effective as the predicate.
CDRH	Center for Devices and Radiological Health — the FDA center responsible for regulating medical devices.
21 CFR Part 807	The Code of Federal Regulations section governing establishment registration, device listing, and 510(k) requirements.
Product Code	A three-letter FDA code identifying a specific device type within the classification system.
PMA	Premarket Approval — the most stringent FDA pathway, required for Class III devices; demands valid scientific evidence (typically clinical trials) of safety and effectiveness.
De Novo	A regulatory classification request for novel low-to-moderate risk devices without a predicate; creates a new device classification and serves as the basis for future 510(k)s.
QMSR	Quality Management System Regulation — the new U.S. device quality system rule effective February 2, 2026, aligned with ISO 13485:2016, replacing the former QSR.
RTA	Refuse to Accept — FDA's administrative screening determination (Day 15) that a submission does not contain the threshold elements required for substantive review.

Key Regulatory References for Chapter 1