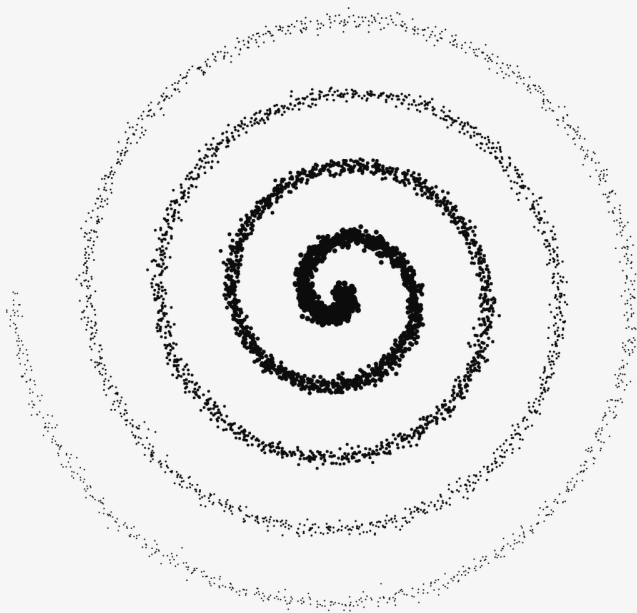




GUIDE 09

MARKET PATHWAYS

How a device reaches the market

510(k), De Novo, PMA, and exemption: what each pathway asked the manufacturer to show, and what that means for the record you can request.



ABOUT

Every device on the US market got there by one of a few routes, and each route asked the manufacturer a different question. The route tells you what FDA saw, what it did not see, and which records exist because the route required them.

This guide explains device classification, the premarket routes, and what each one establishes. It then shows how to find the submission for a specific device, read it, and trace what changed after the decision.

FOR

Legal counsel who need to know what “cleared” or “approved” means for a particular device, and what records the route created.

Manufacturers — regulatory and quality teams who maintain the submission and decide when a change needs a new one.

Hospitals — value analysis and clinical engineering staff who evaluate devices and their labeling.

NOTE

This guide is general technical information. It is not legal or regulatory advice. Terms are taken from the Federal Food, Drug, and Cosmetic Act and 21 CFR Parts 807, 814, and 860 as in force in October 2026.

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SERIES

This guide is one of fifteen practical guides from Alpha Devices. The full list is on the back cover; all are free at alphadevices.io/resources.html.

01

Class decides the route

FDA places every device type in one of three classes by the controls needed to provide reasonable assurance of its safety and effectiveness. The class is set for the device type, not the product, and is published in the classification regulations; FDA assigns each type a product code. The class decides which premarket route is open.

CLASS I	General controls are enough: registration and listing, labeling, a quality system, complaint handling, and reporting. Most Class I types are exempt from premarket notification. Examples: manual instruments, bandages, examination gloves.
CLASS II	General controls plus special controls: performance standards, specific labeling, guidance, postmarket surveillance. Most Class II devices reach the market by 510(k); some types are exempt. Examples: infusion pumps, most patient monitors, ventilators.
CLASS III	Devices that support or sustain life, are of substantial importance in preventing impairment, or present a potential unreasonable risk, where general and special controls are not enough. Premarket approval is required, with a few older types still cleared by 510(k) until FDA calls for approval. Examples: implantable pacemakers, heart valves.
NO CLASS YET	A new type with no classification regulation is Class III by default. The De Novo route asks FDA to create a Class I or II classification for it, with special controls where it is Class II.

NOTE

The class and product code are on the public classification database and in the submission. They lead to the special controls and the guidance that applied, and to every other device of the same type.

FIGURE

Four routes, four questions

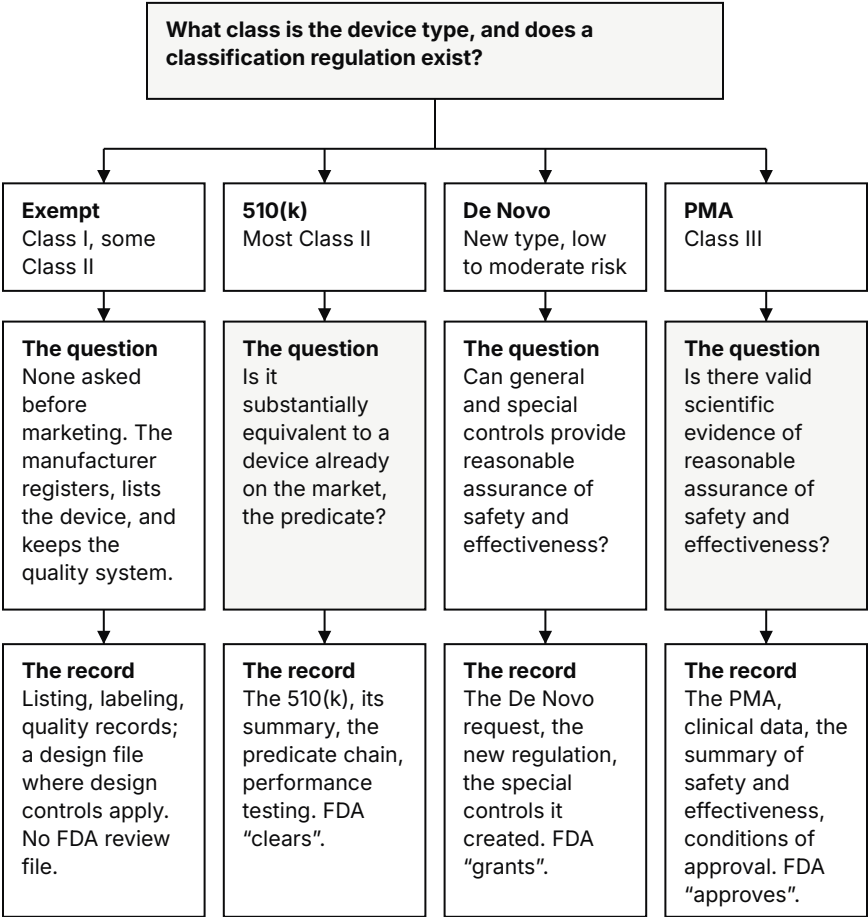


FIG 01

Cleared, granted, and approved are different decisions. Only the PMA route asks FDA to find that the device itself is safe and effective; a 510(k) clearance finds that it is as safe and effective as a predicate.

02

What a 510(k) shows

A 510(k) is a premarket notification. The manufacturer shows that the new device has the same intended use as a legally marketed *predicate* device, and technological characteristics that are the same or raise no different questions of safety and effectiveness. FDA's decision is a finding of substantial equivalence.

01

The predicate chain

The predicate was itself cleared against an earlier predicate. Following the chain back shows where the technology changed and what data supported each step. A chain that ends at a device sold before 1976 ends at a device that was never reviewed.

02

Performance data, not clinical data

Most 510(k)s rest on bench testing, software documentation, biocompatibility, electrical safety, and conformance to recognised standards; clinical data is the exception. The 510(k) summary, public for most clearances, lists what was submitted; the full submission contains it.

03

Changes after clearance

A manufacturer may change a cleared device without a new 510(k) if it decides the change could not significantly affect safety or effectiveness. The decision is a "letter to file" in its own records, answering the questions in FDA's 2017 guidance. The letters are part of the design history (guide 05).

KEY POINT

A clearance is a comparison, as good as the predicate and the testing behind it. The letters to file are where a device moves away from both.

03

PMA and De Novo

01

Premarket approval

A PMA contains the full technical and clinical evidence: device description, manufacturing, non-clinical studies, clinical investigations, labeling. FDA publishes a Summary of Safety and Effectiveness Data (SSED) with the approval order, and the order may carry conditions: post-approval studies, specific labeling, periodic reports.

Changes that affect safety or effectiveness need a PMA supplement; the type of supplement depends on the change. Annual reports list the changes made without one. Both are public in part through the PMA database.

02

De Novo

For a new device type with no predicate and low to moderate risk. If granted, FDA creates a classification regulation and the special controls that every later device of that type must meet. The De Novo decision summary is public and describes the evidence reviewed. Later devices of the type usually arrive by 510(k), with the De Novo device as predicate.

03

Humanitarian device exemption

For devices treating conditions affecting small populations. The standard is probable benefit, not effectiveness, and use is under institutional review board oversight. Rare in practice; distinctive when present.

■ CAUTION

- "FDA approved" in marketing or testimony usually means cleared. The decision letter says which. The difference decides what evidence FDA reviewed and what the manufacturer was required to produce.

04

After the decision

The decision is a point on the timeline (guide 15). The obligations that follow it are where most of the record is made.

01

Registration, listing, and UDI

The establishment registers, the device is listed under its product code, and each version carries a unique device identifier recorded in the public GUDID database. The UDI on the label leads to the listing, the version, and the submission.

02

Labeling

Indications for use are set by the submission. The instructions for use, warnings, and contraindications are part of the device; a change to them is a design change, and may be a correction (guide 14).

03

The quality system

Production records, complaint handling, CAPA, and servicing apply from the first unit, whatever the route; design controls apply to Class II and III devices and to the Class I types FDA lists. Exemption is from premarket review, not from the quality system.

04

Reporting

Adverse events under Part 803 and corrections and removals under Part 806 (guides 13 and 14). FDA may also order postmarket surveillance for certain Class II and III devices under section 522.

05

Changes

Letters to file, new 510(k)s, PMA supplements, and annual reports. Each is a dated decision about whether a change mattered, made by the manufacturer first.

06

The public databases

510(k), PMA, De Novo, classification, GUDID, recalls, MAUDE, and the Total Product Life Cycle view that joins them by product code. Each is reachable from the FDA website, and most through openFDA.

NOTE

Each of these obligations produces a dated record. Together they are the market stream of the timeline in guide 15.

05 Reading the submission

For a specific device, the route and the record are found in this order.

01 Start from the label

Model, catalogue number, UDI, and software version from the device or its labeling. GUDID gives the listing and the product code; the listing names the submissions.

02 Read the public summary

The 510(k) summary, the De Novo decision summary, or the SSED. Note the indications for use, the predicate, the technological characteristics claimed, and the testing listed.

03 Trace the chain

For a 510(k), each predicate in turn, to the point where the technology in question entered the chain and the data that supported it.

04 Compare the indications with the use

The indications for use statement against how the device was used in the matter. Use outside the indications is not itself a defect; it changes which testing and labeling were required.

05 List the testing

Standards cited, with versions; bench tests; software documentation level; usability evaluation. This list is what the design file should contain, and what the request in guide 05 asks for.

06 Find what changed since

New 510(k)s and supplements in the databases; letters to file and annual reports in the manufacturer's record. Place each on the timeline against the complaints and the field actions.

06

Where the route matters most

These are the findings that most often change what the premarket record means for a specific event.

01

A change under letter to file touched the failure mode

The component, the software, or the algorithm involved in the event was changed without a new submission. The letter's reasoning is the record to read.

02

A predicate with different technology

The chain reaches the technology in question through a predicate that did not have it, supported by bench data only.

03

Indications narrower than the marketed use

Training materials, sales literature, or the configuration in the field go beyond the indications in the decision.

04

Standards cited by edition

The submission cites an edition of a standard since revised, or conformance was claimed in part. The test reports show which clauses were run.

05

Conditions of approval not met

A post-approval study not completed, or a required report not filed. The PMA database lists the conditions.

06

Special controls not evidenced

A De Novo or classification regulation requires specific testing or labeling; the design file does not show it.

NOTE

None of these is a conclusion. Each is a place where the premarket record and the event meet, and where the manufacturer's own reasoning is written down.

CHECKLIST

The route at a glance

- ☐ Model, UDI, and software version taken from the device or its labeling
- ☐ Product code, class, and classification regulation identified
- ☐ Route identified: exempt, 510(k), De Novo, PMA, or HDE; decision letter obtained
- ☐ Public summary read: indications, predicate, characteristics, testing
- ☐ Predicate chain traced to where the technology in question entered
- ☐ Special controls, guidance, and recognised standards for the type listed
- ☐ Indications for use compared with the use in the matter
- ☐ Submissions and supplements since the decision listed from the databases
- ☐ Letters to file, annual reports, and change records requested (guide 05)
- ☐ Conditions of approval and postmarket surveillance orders checked
- ☐ Decision, changes, complaints, and field actions placed on one timeline (guide 15)

SOURCES

Sources and further reading

eCFR — 21 CFR Part 807 Subpart E (premarket notification), Part 814 (premarket approval), Part 860 (classification and De Novo)

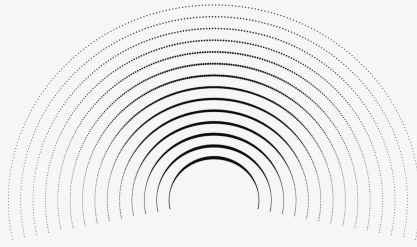
ecfr.gov

FDA — The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (2014); Deciding When to Submit a 510(k) for a Change to an Existing Device (2017)

fda.gov

FDA — 510(k), PMA, De Novo, Product Classification, GUDID, and TPLC databases

fda.gov



SERVICES

We read the submission as the engineers who would have written it

We trace the predicate chain, compare the testing listed with the design file, and find the changes made between the decision and the event.

01

Route and record

The classification, the decision, the public summaries, and the list of records the route required the manufacturer to keep.

02

Changes since clearance

Letters to file, supplements, and change orders read against the failure mode, and placed on the timeline.

03

Testing against the claim

Where a submission claims conformance to a standard, we run the clauses that matter on the device in question and on an exemplar.

TERMS

Terms used in this guide

Classification

FDA's placement of each device type in Class I, II, or III by the controls needed for reasonable assurance of safety and effectiveness.

510(k)

A premarket notification showing that a device is substantially equivalent to a legally marketed predicate. FDA clears it.

Predicate

The legally marketed device a 510(k) compares itself to, for intended use and technological characteristics.

Substantial equivalence

FDA's finding that a new device is as safe and effective as its predicate: the same intended use, and the same technology or technology that raises no new questions.

PMA

Premarket approval: FDA's review of valid scientific evidence that a Class III device is safe and effective. FDA approves it.

De Novo

A request that FDA create a Class I or II classification for a new device type with no predicate, with special controls where it is Class II. FDA grants it.

Special controls

Requirements for a Class II device type beyond general controls: performance standards, labeling, guidance, postmarket surveillance.

Letter to file

A manufacturer's internal record of its decision that a change did not require a new 510(k) or a PMA supplement.

Tell us about the device.

Send a short description of the device, the event, and any deadlines. We will tell you what to preserve now and recommend the next steps.

EMAIL info@alphadevices.io

WEB alphadevices.io

GUIDES

- | | | | |
|----|-------------------------------------|----|--|
| 01 | A device failed. What happens next? | 09 | How a device reaches the market |
| 02 | Searching MAUDE with purpose | 10 | Why the alarm did not help |
| 03 | Understanding waterfall design | 11 | When the software is the suspect |
| 04 | Reading an ISO 14971 risk analysis | 12 | Use error is a design question |
| 05 | The manufacturer's record | 13 | Complaints, MDRs and CAPA |
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