Report

Evidence review

Updated
22 October 2026

Clinical Evidence in Medical Device Marketing: what the rules allow and what it costs

What FDA and the FTC let a device company say about its studies, and the price of the evidence behind each claim

What a device company says is evidence of what the device is for, and a health claim needs evidence a regulator would accept. The pivotal study behind that evidence averages $30.7 million for a complex device.

Download the report (PDF) **Key findings →**

How it was done →

Updated
22 October 2026

Sources
12 primary sources, all opened 22 Oct 2026

Scope
US rules: FDA, FTC, ClinicalTrials.gov

Evidence window
Rules in force in Oct 2026; studies 2015 and 2022

Status
General information, not legal advice



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13 min read **6** chapters **7** figures **12** references

A medical device startup usually learns what its evidence is worth at the worst moment: when a hospital committee asks for a study, or when a draft claim reaches a regulatory reviewer. I set out to answer two questions from primary sources only. What may a device company say about its evidence, and what does building that evidence cost?

Key findings

Each finding is tagged with the kind of source behind it. All sources were opened on 22 October 2026.

01 **Federal regulation**

Any

statement on the website, in a deck or from a sales representative can define the use FDA holds the device to.

Chapter 1 →

02 **FDA guidance**

Paused

FDA's January 2025 guidance on sharing studies about uncleared uses is not for current implementation, pending OMB.

Chapter 2 →

03 **Peer-reviewed estimate**

$30.7M

average out-of-pocket cost of a pivotal study for a complex device: 565 patients over about 57 months.

Chapter 4 →

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04 **Peer-reviewed study**

13 of 30

pivotal studies for high-risk devices approved in 2010 and 2011 had no comparison group.

Chapter 4 →

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05 **FDA notice**

4.5%

is FDA's 510(k) fee as a share of the PMA fee: $28,653 against $636,732 in fiscal 2027.

Chapter 4 →

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06 **Federal regulation**

21 days

to register an applicable device trial after the first participant is enrolled.

Chapter 5 →

How this report was made

An evidence review, not a survey. The sample is 12 primary sources: four federal regulations, three FDA and FTC guidance documents, one FDA fee notice, two peer-reviewed studies and two journal fee pages. Only primary sources were included; each was opened on 22 October 2026, and quotations are taken from

the source itself. Cost figures cover complex devices approved through PMA, in 2018 dollars.

Full method and limits →

Executive summary

The rules on what a device company may say are stricter than most marketing teams assume, because FDA reads intended use from everything the company says, not only from its labeling. Inside the clearance, a study can be cited if it is sound and its limits are disclosed; outside it, the path is narrow and the governing guidance is not yet in force.

The FTC adds its own test for any health claim, and it generally means controlled human testing with a clinically meaningful result. That standard, not the marketing calendar, decides which claims a startup can make.

Evidence is expensive at the top of the ladder and cheap at the bottom. The public cost data covers complex PMA devices only, so a 510(k) startup should treat it as a ceiling and plan the cheaper local evidence first.

Read this if

You market a medical device in the US and want to know which claims your evidence supports today.

Use it to

Write a claims table before you design a study, and size the evidence budget for your route.

It will not tell you

Whether a specific claim is lawful for your device. That is for your regulatory adviser.

Contents 6 chapters

Key findings

Executive summary

1 Your marketing defines the device
2 Claims inside and outside the clearance
3 The FTC standard for health claims
4 What the evidence costs
5 Registering a study
6 Publishing and cheaper evidence
What this means for you
Method and limits
Data and citation

Chapter 1 of 6

Your marketing defines the device

FDA decides what a device is intended for by looking at what the people responsible for it say and do. The regulation says intended uses “refer to the objective intent of the persons legally responsible for the labeling of an article,” and that the intent “may be shown by such persons’ expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article.” It names “labeling claims, advertising matter, or oral or written statements by such persons or their representatives” as ways to show it.[1]

Figure 1

Five kinds of statement, five rules: the website and sales team can define the use FDA holds you to

What you are saying	The rule	What it means in practice
Anything about the device, anywhere	21 CFR 801.4: intended use is the objective intent shown by labeling, advertising and statements	The website, deck and sales team define the use FDA holds you to
A claim about the cleared use that cites a study	FDA guidance, June 2018	Allowed if consistent with labeling data are scientifically appropriate a statistically sound, and material limitations are disclosed
A publication about a use FDA has not cleared	FDA guidance, January 2025	Narrow conditions, and the guidan not for current implementation per OMB
A health benefit, to anyone	FTC Health Products Compliance Guidance, 2022	Competent and reliable scientific evidence, generally randomized controlled human testing
Your FDA status	21 CFR 807.97; FTC example	Clearance does not denote approv "FDA Approved" beside outcome c on a cleared device was found deceptive

Rules from 21 CFR 801.4[1], FDA guidance[2,3], 21 CFR 807.97[4] and the FTC[5]. The last column is AAJ's summary, not a legal test.

Read the table from left to right: each row is a kind of statement you might make, the rule that governs it, and what that rule means in practice. The first row sets up the others: your website, sales deck, conference poster and a sales representative's answer in a hospital corridor all count as evidence of intended use. In my view, a claim you would not put in a regulatory submission should not appear in marketing either.

Inside the clearance you can cite a sound study; outside it, the path is narrow

Companies may talk about studies that support a cleared use, with limits. FDA's June 2018 guidance on communications consistent with FDA-required labeling says that “any data, studies, or analyses relied on should be scientifically appropriate and statistically sound,” and that firms should not “fail to disclose their material limitations.”[2]

Describing the regulatory status needs the same care. For a device cleared through 510(k), the regulation says clearance “does not in any way denote official approval of the device” and that any representation creating “an impression of official approval” because of the notification “is misleading and constitutes misbranding.”[4] The FTC's own example is an electronic muscle-stimulation belt cleared as a Class II device and advertised as “FDA Approved” beside weight-loss claims; the FTC found the advertising deceptive because the pairing implied FDA had found the device effective for those effects.[5]

Sending publications about an uncleared use is the narrowest path. In January 2025 FDA issued guidance on communications from firms to health care providers about scientific information on unapproved uses, replacing its 2009 guidance on distributing journal articles. FDA's page states that the guidance “is not for current implementation, pending the Office of Management and Budget’s (OMB’s) decision on the collection of information.” That wording was still on the page on 22 October 2026.[3]

A pilot with 20 patients and no comparison group can be described honestly as exactly that, but it cannot carry a headline outcome. Say “FDA cleared” when that is what happened, and keep it away from outcome claims. Until the 2025 guidance takes effect, route every question about an

uncleared use to a trained medical or regulatory person, never to a salesperson with a PDF.

Chapter 3 of 6

A health claim needs controlled human evidence with a result that matters

The FTC applies its own test to health benefit claims made to anyone. Its Health Products Compliance Guidance defines “competent and reliable scientific evidence” as research that has “been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function” and is “generally accepted in the profession to yield accurate and reliable results.” It adds that “as a general matter, substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing,” that results must be “clinically meaningful” as well as statistically significant, and that “there is no requirement for a specific number of RCTs,” although independent replication adds weight.[5]

Figure 2

The study behind a claim sets how far the claim can go

A single-site evaluation

Process or cost against a comparison unit

Can support

A measured change in the process or cost, at that site

Cannot support

Any claim about patient outcomes

A small feasibility study

Early use, limits stated

Can support

That the approach works in early use, with the limits stated

Cannot support

A headline outcome, or a comparison with other devices

A controlled human study

In the cleared population, clinically meaningful result

Can support

An outcome claim inside the clearance, with material limitations disclosed

Cannot support

A claim for a use or population outside the clearance

AAJ's reading of the FDA and FTC standards [2,5], set out as a working rule. It is not a legal test.

Put together, an outcome claim needs a controlled human study you could hand to a regulator, in the population your clearance covers, with a result large enough to matter to a patient. A single-site evaluation of nurse time or supply use can support a claim about nurse time or supply use. It cannot support a claim about infections.

The pivotal study is the largest single cost, and real pivotal evidence is thinner than assumed

The best public estimate of device evidence costs covers complex devices that need premarket approval. Researchers at Eastern Research Group built a cost model from 151 such devices among the 191 PMAs approved from January 2013 to September 2018.[6]

Figure 3

For a complex device, the pivotal study is the largest single out-of-pocket cost

Nonclinical development
Expert-opinion assumption in the model

$20.0M

Feasibility study
42 patients, 28 months

$1.4M

Pivotal study
565 patients, about 57 months, $54,332 a patient

$30.7M

FDA submission and review
PMA review stage

$1.9M

Mean out-of-pocket cost

$54M

The four stages above, 2018 dollars

Moved on to a pivotal study

48%

Of devices in the feasibility sample

Mean capitalized cost

$522M

Including failures and the cost of capital

Show the numbers as a table

Nonclinical

Out-of-pocket cost (2018 dollars)	$20,000,000
Basis	Expert opinion

Feasibility study

Out-of-pocket cost (2018 dollars)	$1,428,249
Basis	42 patients × $34,059

Pivotal study

Out-of-pocket cost (2018 dollars)	$30,672,652
Basis	565 patients × $54,332

FDA PMA review

Out-of-pocket cost (2018 dollars)	$1,852,816
Basis	AdvaMed

Postapproval study (not in the $54M)

Out-of-pocket cost (2018 dollars)	$5,961,197
Basis	414 patients × $14,416

Sertkaya et al. (2022), cost model for therapeutic complex devices: 151 of the 191 PMAs approved from January 2013 to September 2018; 2018 dollars. The four stages sum to about $54 million and exclude postapproval studies; the nonclinical amount is an expert-opinion input.[6]

The bars are drawn to the same scale, so the pivotal study, at about $30.7 million, is longer than the other three stages combined. The dark card is a different measure: the $522 million capitalized cost adds the devices that failed along the way and the cost of the money tied up meanwhile, and the authors report that the nonclinical stage accounts for 85% of it.[6] Fewer than half of the devices went on to a pivotal study, so in my view the feasibility study is a real decision point, and the $30.7 million is a ceiling for complex devices rather than a budget for yours.

About this data

The nonclinical $20 million is an expert-opinion assumption in the model, so read the split between stages as a reasoned estimate, not a measurement. The figures are in 2018 dollars and cover complex PMA devices only.

Published pivotal evidence is also thinner than founders often assume, as a 2015 JAMA study of the 28 high-risk therapeutic devices approved through PMA in 2010 and 2011 shows.[7]

Figure 4

13 of 30 pivotal studies for high-risk devices had no comparison group



Median enrolment in a pivotal study: 241 patients.

Rathi, Krumholz, Masoudi and Ross (2015), JAMA: the 28 high-risk therapeutic devices approved through PMA in 2010 and 2011, with 30 pivotal studies.[7]

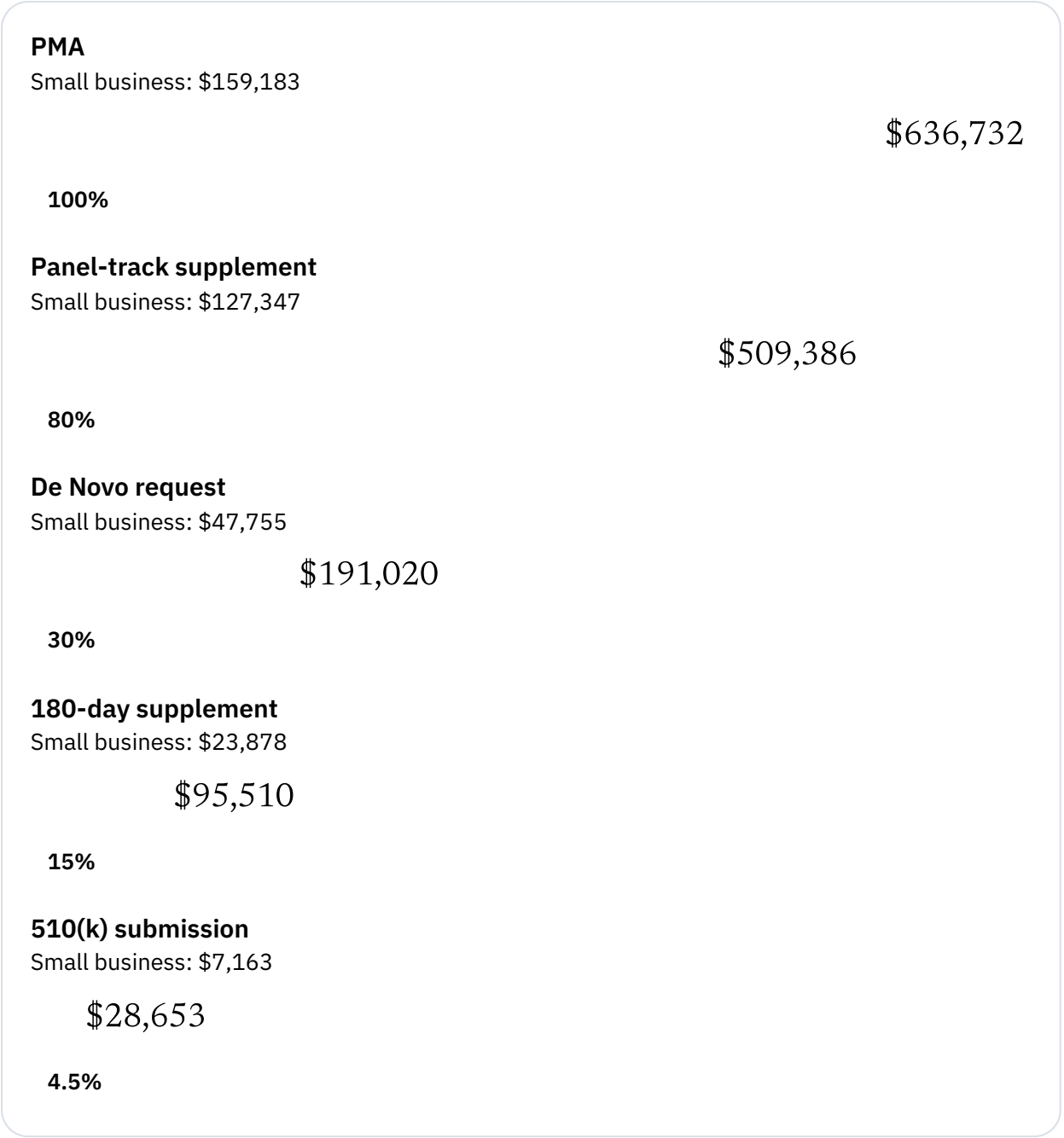
Each square is one pivotal study; the 13 filled squares, 43.3% of the 30, had no comparison group, and the median study enrolled 241 patients. These are the studies behind approvals of high-risk devices, not early pilots. In my view, a hospital committee that has seen this evidence base will not expect a startup to arrive with a large randomized trial, but it will notice whether you describe your own study's limits honestly.

Most startups do not take the PMA route. For a 510(k), the study requirement is usually smaller, and I found no primary estimate of

what 510(k) clinical studies cost. What is public is FDA's fee for the submission itself.[8]

Figure 5

FDA's fee for a 510(k) is 4.5% of the fee for a PMA



Show the numbers as a table

PMA

Standard fee	$636,732
Small business fee	$159,183

Panel-track supplement

Standard fee	$509,386
Small business fee	$127,347

De Novo classification request

Standard fee	$191,020
Small business fee	$47,755

180-day supplement

Standard fee	$95,510
Small business fee	$23,878

510(k) premarket notification

Standard fee	$28,653
Small business fee	$7,163

FDA, Medical Device User Fee Rates for Fiscal Year 2027, effective 1 October 2026, read from the notice as posted for public inspection; each tag is the fee as a share of the PMA fee. The annual establishment registration fee is $13,785.[8]

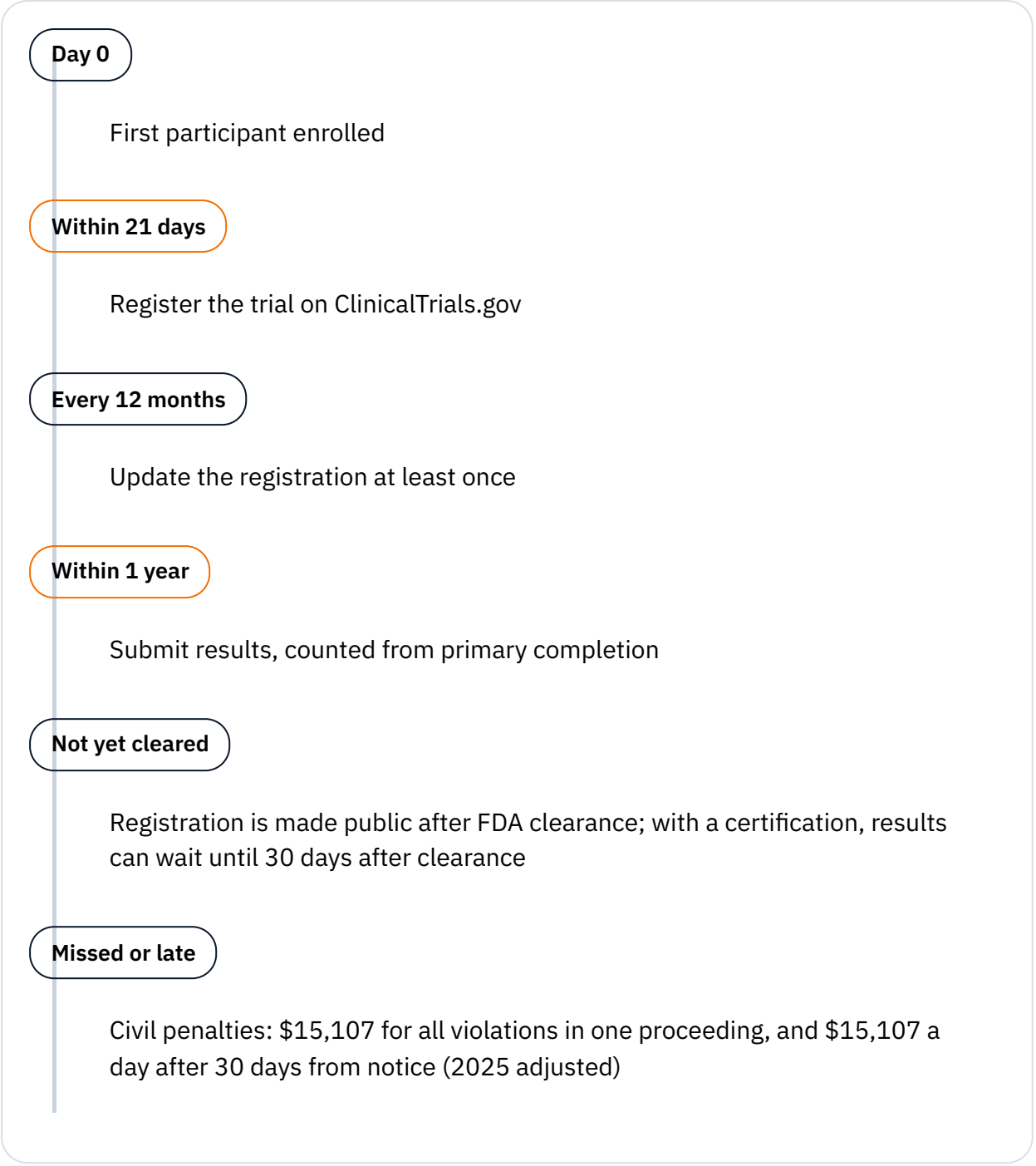
Each bar is a standard FY2027 fee, and the tag shows it as a share of the PMA fee: a 510(k) costs $28,653, or 4.5% of a PMA's $636,732, and a small business pays about a quarter of each. The fee is the small part of the bill; the study behind the submission is the large one. In my view, size your evidence plan to your route and the claims you want with your regulatory adviser, not to the fee.

A controlled outcome study must be registered within 21 days

If a study is large enough to matter commercially, it is probably also an "applicable device clinical trial." Under 42 CFR Part 11 that means a prospective study of health outcomes that compares an intervention with a control, for a device subject to 510(k), PMA or humanitarian device exemption review, other than a small feasibility study.[9]

Figure 6

An applicable device trial runs on a fixed clock from the first participant



42 CFR Part 11 [9]; penalty amounts from 45 CFR 102.3, which HHS adjusts every year. [10] Applies to controlled studies of health outcomes, not small feasibility studies.

Read the timeline from the top: the clock starts with the first participant, registration is due within 21 days, the record is updated at least every 12 months, and results are due within a year of primary completion. Only

controlled studies of health outcomes are covered, so a small feasibility study or a site evaluation is not. In my view, the practical step is to give one person the registration date before enrolment opens, because the deadline runs from an event a clinical site controls.

The penalty for missing these duties is set in statute at up to $10,000 and adjusted each year for inflation. In HHS's 2025 table the figure is $15,107 for all violations in a single proceeding, and the same amount for each day a violation continues after 30 days from notice.[10]

Chapter 6 of 6

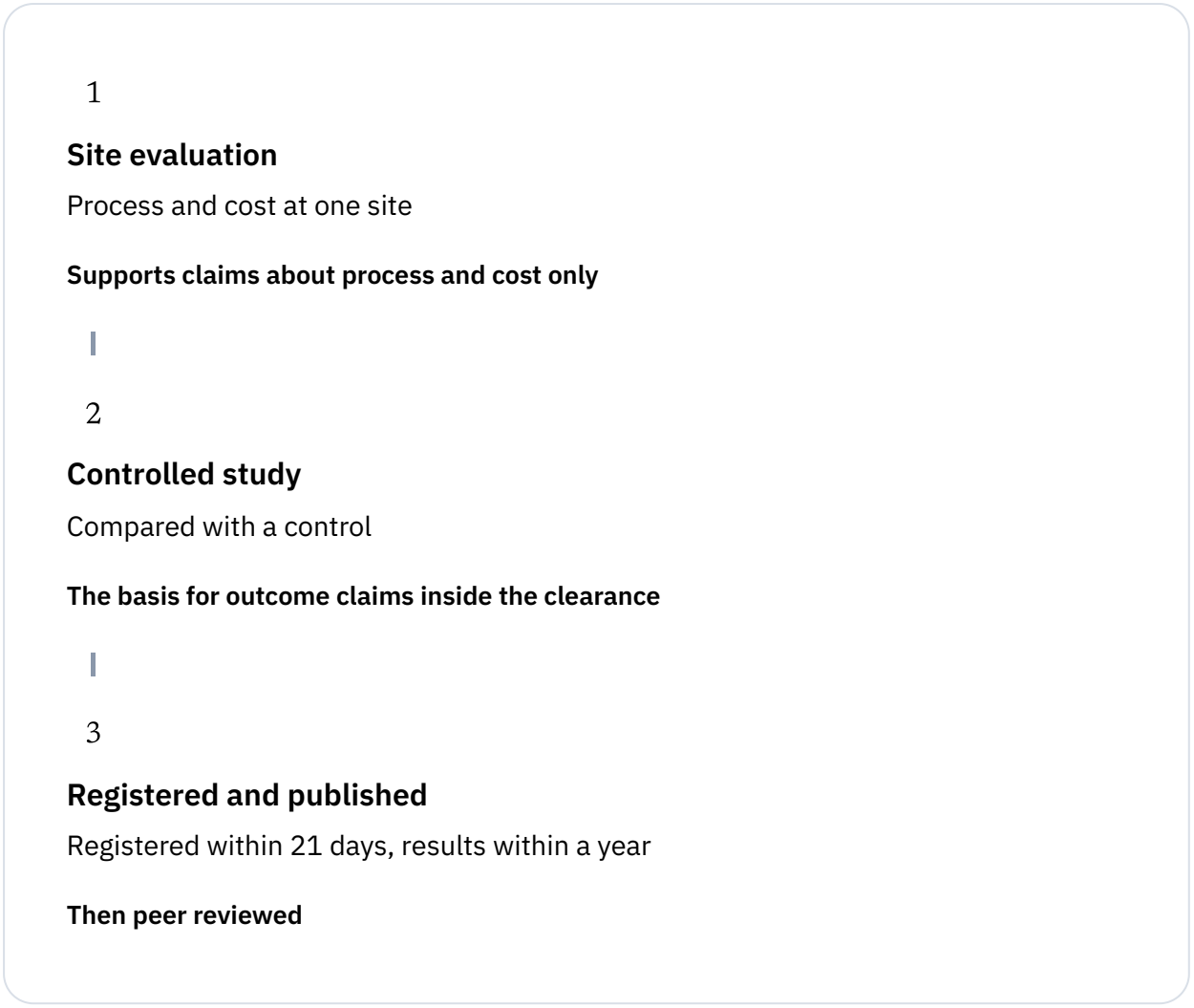
Publishing is cheap next to the study, and local evidence comes first

A peer-reviewed paper is what lets a value analysis committee, and the FTC, take a result seriously. Open-access fees are modest next to the study itself: JAMA Network Open charges $4,000[11] and PLOS ONE lists $2,477.[12]

Most startups begin with evidence that costs a fraction of a clinical study: a single-site evaluation that measures process and cost against a comparison unit, such as dressing changes or nurse time per patient. It is often what a hospital committee asks for first. It cannot support an outcome claim, and anything published from it stays inside the clearance.

Figure 7

Start with local evidence, then build toward evidence you can publish



AAJ's staging, built on the FTC's expectation of controlled human testing for health claims [5] and on 42 CFR Part 11. [9]

Read the chain from left to right: each step supports a wider claim than the one before, and the highlighted step is the one a hospital committee or the FTC can rely on. A site evaluation earns the right to talk about process and cost at that site; a controlled study earns outcome claims inside the clearance; registration and publication make those claims checkable by others. In my view, a startup should plan the second step while running the first, so the site evaluation also tells you what a controlled study needs to measure.

What this means for you

Write the claims table before the study: list the claims you want to make, check each against your indication, and design studies to support the ones inside it. What comes next depends on your stage.

Pre-seed

Keep claims to what a site evaluation can show: process and cost at that site. Say “FDA cleared” only when it is true, and never next to an outcome claim.

Seed

Run a measured evaluation at a customer site to win the first committees. If a study compares outcomes against a control, start the 21-day registration clock on day one.

Series A–B

Budget for a controlled study sized to your route and claims, with results due within a year of completion and a peer-reviewed paper to follow.

Keep publications about uncleared uses out of sales hands until FDA's 2025 guidance is in force, and send those questions to a trained medical or regulatory person.

Method and limits

Sample

12 primary sources: 4 federal regulations, 3 agency guidance documents, 1 FDA fee notice, 2 peer-reviewed studies, 2 journal fee pages

Inclusion

Primary sources only: the regulation, guidance or study itself, never a summary of it

Date checked

Every source opened on 22 October 2026; FDA's 2018 guidance read from the PDF

Evidence window

Rules in force in October 2026; cost model on PMAs approved January 2013 to September 2018; JAMA study on PMAs from 2010 and 2011

Currency

Cost model in 2018 dollars; user fees for fiscal year 2027; penalties as adjusted for 2025

Excluded

BMJ Open's fee, because its official page could not be opened

Quotations are copied from the source. Where I summarise a rule, the figure says so. The user fees are from the fiscal 2027 notice as posted for public inspection by the Federal Register.[8]

What this report cannot tell you

- The cost model covers complex devices approved through PMA only; no primary estimate of 510(k) clinical study costs was found.
- The nonclinical cost is an expert-opinion input in the model, not a measurement.
- The JAMA study reviewed devices approved in 2010 and 2011; current pivotal studies may differ.
- Guidance status can change; the 2025 guidance was not for current implementation on 22 October 2026.
- This is general information, not legal or regulatory advice.

Data and citation

Every figure in this report can be traced to the reference list. The fee and cost tables are reproduced in full under each figure.

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All chapters, figures and references

Figure data
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Jha, S. (2026). *Clinical Evidence in Medical Device Marketing: What the Rules Allow and What It Costs*. AAJ. https://aajconsult.com/reports/medical-device-clinical-evidence

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@techreport{jha2026clinical,
  author = {Jha, Saroj},
  title = {Clinical Evidence in Medical Device Marketing: What the Rules Allow and What It Costs},
  institution = {AAJ},
  year = {2026},
  url = {https://aajconsult.com/reports/medical-device-clinical-evidence}
}
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Independence. No sponsor. AAJ sells marketing strategy services to MedTech startups, so it has an interest in this topic; every rule and figure links to its primary source so it can be checked.

Version history

22 October 2026

Every source re-opened and checked; fiscal 2027 FDA user fees added.

26 October 2026

Restructured as a report with key findings, a method section and evidence tags. No figures changed.

Questions founders ask

Can a medical device startup use peer-reviewed papers in its marketing?

Yes, for the use FDA has cleared, if the data are scientifically appropriate and statistically sound and the study's material limitations are disclosed. For uses FDA has not cleared, the January 2025 guidance is not for current implementation pending OMB, so route those questions to a trained medical or regulatory person.

What does it cost to run a clinical study for a medical device?

The best public estimate covers complex devices that need premarket approval: about $30.7 million for a pivotal study of 565 patients over about 57 months, in 2018 dollars. A 510(k) device usually needs less, but no primary cost estimate for 510(k) clinical studies was found.

Does a clinical study have to be registered on ClinicalTrials.gov?

A controlled study of health outcomes for a device subject to 510(k), PMA or humanitarian device exemption review is an applicable device clinical trial, unless it is a small feasibility study. It must be registered within 21 calendar

days after the first participant is enrolled, and results are due within one year of primary completion.

Can I say my 510(k) device is FDA approved?

No. FDA's regulation says that notification and clearance do not denote official approval, and any representation creating an impression of official approval is misleading. Say “FDA cleared” when that is what happened.

What evidence does the FTC expect for a health claim?

Competent and reliable scientific evidence, generally randomized controlled human clinical testing, with results that are statistically significant and clinically meaningful. The FTC sets no fixed number of trials, though independent replication adds weight.

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References

The superscript numbers in the report match this list. Every source was opened on 22 October 2026.

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Written by Saroj Jha

Founder of AAJ

Saroj has spent more than ten years in marketing strategy. He writes AAJ's reports in his own voice. Every figure is referenced, and where a report gives his view it says so.

About the founder →

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