

Device Submission (510(k), De Novo, PMA)

Plan an FDA 510(k), De Novo request or PMA: the substantial equivalence decision against the predicate, the content the pathway needs, the performance testing and the MDUFA review goal.

WRITES

eSTAR

PMA

PRODUCT TYPE

Medical devices

GUIDANCE IT FOLLOWS

21 CFR 807
Subpart E (510(k));
21 CFR 860
Subpart D (De
Novo); 21 CFR 814
(PMA); FDA The
510(k) Program:
Evaluating
Substantial
Equivalence (2014);
FDA eSTAR
guidance (2023);
FDA Acceptance
Review for De Novo
Classification
Requests (2019);
MDUFA V
performance goals;
FDA Benefit-Risk
Factors guidances
(2019); FD&C Act
513(f)(2), 515, 524B

TIME TO LEARN

About 20 minutes
with the example

Open the tool at <https://app.cmcfy.com/app/device-submission.html>. This guide is also online at <https://cmcfy.com/guides/device-submission.html>

1. What this module does

You choose the pathway and class, describe the device and its indications for use, compare it with the predicate characteristic by characteristic, and list the performance tests and the status of each part of the submission.

For a 510(k) the tool follows FDA's substantial equivalence decision: same intended use, then whether differences raise different questions of safety and effectiveness, then whether data supports each difference. It lists the content for the pathway (biocompatibility, sterility, software, cybersecurity and EMC when they apply) and gives the MDUFA goal in FDA days.

What you get

- A Word or PDF file: 510(k) summary with the substantial equivalence discussion, or the De Novo or PMA summary.

2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- The predicate 510(k) number and its labeling.
- Performance test reports.
- The eSTAR content list.

Your data stays on your computer. The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. [Download offline](#) [copy](#) saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

3. Step by step with the example

Open the tool at app.cmcfy.com/app/device-submission.html. The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

1 Describe the device and pathway

Choose 510(k), De Novo or PMA and the class, and tick what applies: sterile, patient contact, software, cyber device, electrical.

CMCfy | Device Submission (510(k), De Novo, PMA) | Projects | All modules | Training | Security

Runs entirely on this device | **Training guide**

PROJECTS Keep this work in a project, with version history and your company logo on every report. Choose projects folder Keep in this browser

- Network requests since load: 0**
Counted live by your browser. Your data never leaves this device.
- Works offline**
Everything the tool needs is inside this page.
- Locked offline copy**
Save a single file that opens from your own computer with all network access blocked.

eSTAR | **PMA** Save project Open project Start blank Load example

Plan an FDA device submission: a 510(k), a De Novo request or a PMA. For a 510(k) the tool walks the substantial equivalence decision against the predicate; for every pathway it lists the content needed, checks the performance testing and the support for each difference, and dates the MDUFA review goal.

Guidance: 21 CFR 807 Subpart E (510(k)); 21 CFR 860 Subpart D (De Novo); 21 CFR 814 (PMA); FDA The 510(k) Program: Evaluating Substantial Equivalence (2014); FDA eSTAR guidance (2023); FDA Acceptance Review for De Novo Classification Requests (2019); MDUFA V performance goals; FDA Benefit-Risk Factors guidances (2019); FD&C Act 513(f) (2), 515, 524B

1 · DEVICE AND PATHWAY

Device

CMX FlowSense infusion monitor

Submitter

CMX Devices Inc., Raleigh

Pathway

510(k)

Device class

Class II

Product code and regulation

FRN · 21 CFR 880.5725 (infu

Indications for use

Monitors the flow rate of gravity and pump infusions in adult

RESULT

510(k): substantially equivalent to the predicate

11 of 13 content items complete; MDUFA goal 90 FDA days (about 2027-05-02 without hold time).

PATHWAY	READY	TESTS PASSED
510(k)	11/13	7/7
FDA DAYS	90	

COMPARISON WITH THE PREDICATE

2 Compare with the predicate

One row per characteristic. Mark each difference and give the data that addresses it.

3 Read the result

The headline gives the decision: "510(k): substantially equivalent to the predicate".

COMPARISON WITH THE PREDICATE

CHARACTERISTIC	SUBJECT	PREDICATE	DIFFERENT	SUPPORTING DATA
Intended use	Flow monitoring with alarms	Flow monitoring with alarms	no	–
Sensing principle	Ultrasonic transit time	Ultrasonic transit time	no	–
Flow range	0.1–999 mL/h	1–999 mL/h	yes	Bench accuracy testing at 0.1–1 mL/h (TR-114)
Connectivity	Wi-Fi to hospital EHR	None	yes	Cybersecurity testing and threat model (TR-120); wireless coexistence (TR-121)
Patient contact	Tubing clamp (indirect)	Tubing clamp (indirect)	no	–

Comparison with the predicate and the content list.

4

Resolve alerts and download

A new intended use, differences that raise different questions, a failed test, a class III device in a 510(k) and missing core content are critical. Differences without data and open items are flagged. Then preview and download.

Preview and review before download

Close

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

2 to fix

DATA AND INPUTS (2)

510(k) summary or statement: in progress.

Complete it before submission.

major · Content · 21 CFR 807.92, 807.93

Ignore

Cybersecurity (FD&C Act 524B): in progress.

Complete it before submission.

major · Content · FDA Cybersecurity in Medical Devices guidance (2025)

Ignore

Compare with the protocol

Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in the report.

Paste the protocol text here, or load the file.

Load protocol file

Compare

AI review against guidance

AI reads the report, the protocol and the data against the ICH, FDA or EMA requirements for these sections, and lists gaps.

510(k) 510(k) summary and substantial equivalence

CMX FlowSense infusion monitor · CMX FlowSense infusion monitor · class 2

Submitter	CMX Devices Inc., Raleigh NC
Device	CMX FlowSense infusion monitor
Class and product code	Class 2 · FRN · 21 CFR 880.5725 (infusion pump)
Pathway	510(k)
Predicate	InfuWatch 2 (K213456)
Indications for use	Monitors the flow rate of gravity and pump infusions in adults in hospitals and alerts the clinician to occlusion and free flow.

Comparison with the predicate

Characteristic	Subject device	Predicate	Supporting data
Intended use	Flow monitoring with alarms	Flow monitoring with alarms	Same
Sensing principle	Ultrasonic transit time	Ultrasonic transit time	Same
Flow range	0.1-999 mL/h	1-999 mL/h	Bench accuracy testing at 0.1-1 mL/h (TR-114)
Connectivity	Wi-Fi to hospital EHR	None	Cybersecurity testing and threat model (TR-120); wireless coexistence (TR-121)
Patient contact	Tubing clamp (indirect)	Tubing clamp (indirect)	Same

Performance testing

Test	Standard or method	Result
Flow accuracy	TR-114 (±5% at 0.1-999 mL/h)	Pass

Fix or justify the 2 blocking alerts before downloading. Or choose "Download anyway".

Download anyway

Download Word (.docx)

Download PDF

Document text

4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies” appear only for the choices that need them.

1 · Device and pathway

FIELD	WHAT TO ENTER
Device	Type it in.
Submitter	Type it in.
Pathway	Choose one: 510(k); De Novo; PMA.
Device class	Choose one: Class I; Class II; Class III.
Product code and regulation	Type it in.
Indications for use	Type it in.
Sterile or has a shelf life	Tick the box if it applies.

FIELD	WHAT TO ENTER
Patient-contacting materials	Tick the box if it applies.
Contains software	Tick the box if it applies.
Cyber device (connects to the internet or a network)	Tick the box if it applies.
Electrically powered	Tick the box if it applies.
Clinical data included when it applies	Tick the box if it applies.
Advisory panel expected when it applies	Tick the box if it applies.
Planned submission date	Type it in.

2 · Predicate and comparison

For a 510(k): one row per characteristic. Different: yes when it differs from the predicate; give the data that addresses each difference.

FIELD	WHAT TO ENTER
Predicate device (510(k) number) when it applies	Type it in.
Same intended use as the predicate when it applies	Tick the box if it applies.
Differences raise different questions of safety or effectiveness when it applies	Tick the box if it applies.
Comparison	Write "yes" in Different only when the characteristic differs from the predicate. A table. Columns: Characteristic Subject device Predicate Different (yes/no) Data addressing the difference. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Testing and content

FIELD	WHAT TO ENTER
Performance testing	A table. Columns: Test Standard or method Result (pass/fail). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Submission content	A table. Columns: Item Status. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- Substantial equivalence decision.
- Performance testing and support for each difference.
- Content by pathway and MDUFA goal.

How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press **Record**.
- **Major** alerts block the download until you fix them or type a justification and press **Accept justification**.
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.
- Some alerts have an **Apply fix** button that makes the change for you. **Reopen** undoes a justification.

Narratives

This module writes: Substantial equivalence or summary. Each narrative is written by fixed rules from your data. You can edit it in the box. **Rewrite with AI** (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is flagged under the box and blocks the download until you correct it. **Reset to rule-based text** brings back the original.

6. Preview, gap review and download

1. Press **Preview** next to a section, or **Preview and download all**. The document opens in a preview window, exactly as the Word file will read.

- The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left in the text) and, if you load the approved protocol under **Compare with the protocol**, **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).
- Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
- Optional **AI review**: a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
- Press **Download Word (.docx)** or **Download PDF**. With several documents open, **All as Word (.zip)** and **All as PDF (.zip)** download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

Documents this module produces

SECTION	DOCUMENT
510(k) / De Novo / PMA	Submission summary

Use **Save project** to keep your work as a file on your computer, and **Open project** to continue later. **Start blank** clears every field; **Load example** brings the example back. Nothing is stored on CMCfy servers.

7. US and EU submissions

US only: FDA 21 CFR 807, 814 and 860. For the EU, the technical documentation follows EU MDR Annexes II and III.

8. Working with other modules

- Trace design controls in the Design History File and write the Risk Management Report.

9. Common pitfalls

- A predicate with a different intended use.
- A connected device without the 524B cybersecurity information.

10. Practice exercises

Each exercise starts from the example (press [Load example](#) to reset). We run these on every update of this guide, so the result you see should match.

1. **Change the intended use**

Untick "Same intended use as the predicate".

EXPECTED RESULT

The headline shows a critical issue: not substantially equivalent.

Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.