

How to Determine Your HF Submission Category

Two paths in eSTAR: **Manual selection** or **"Guide Me"** — a 3-question flow that walks you through to the right category.

Option A — Manual Selection

Consult the FDA *HF Content Guidance* and pick your category directly from the eSTAR dropdown:

Category 1

Section 1 of HFE/UE report only

Category 2

Sections 1–4 of HFE/UE report

Category 3

Sections 1–8 of HFE/UE report (full validation)

Documentation may be placed in bench testing, clinical evidence, or other appropriate sections.

Option B — "Guide Me" (Recommended if unsure)

Q1 — DECISION POINTS A & B

No change to user interface?

Answer **Yes** if: previously-authorized device with no change to UI, intended users, use, environment, training, or labeling — *or* new device with no such changes vs. your own legally-marketed device.

— YES ►

→ **Category 1**

NO ↓ (proceed to Q2)

Q2 — DECISION POINT C (URRA)

No critical tasks affected?

Answer **Yes** if: URRA shows the new device has no critical tasks — *or* URRA confirms no new/impacted critical tasks on the modified device.

— YES ►

→ **Category 2**

Critical task = incorrect performance could cause serious patient or user harm.

NO ↓ (proceed to Q3)

Q3 — HF VALIDATION TESTING

Should HF validation test data be submitted?

Consider: history of safe use of this UI; UI complexity; adequacy of existing risk controls.

If UI is not complex and has an established safe-use history → may not need to submit validation test data.

— YES ►

→ **Category 3**

— NO ►

→ **Category 2**