MEDDEV ADVISORY

SAMPLE PREVIEW

FDA 510(k) Biocompatibility Section Builder

Device-specific evidence, report, eSTAR, attachment, and review controls

An honest view of the FDA working sequence, files, controls, and professional-judgment boundary

MDA-TLK-FDA-BIO-510K-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams assemble a traceable FDA 510(k) biocompatibility working section from controlled device information, current evidence, complete reports, recognition records, and named reviewer decisions.

A structured working aid. It does not determine biological safety, compliance, or regulatory acceptance.

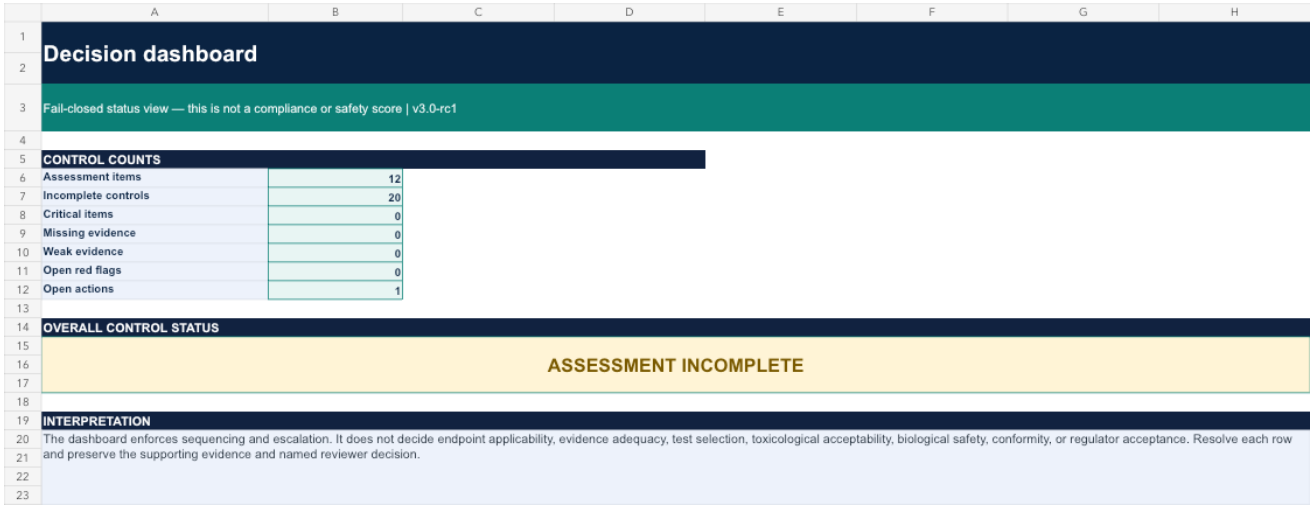
What this resource helps a team produce

- A controlled 510(k) submission scope tied to the exact final finished device, indications, variants, contact route, duration, sterilization, packaging, ageing, and manufacturing state.
- A device-category and contact-duration record that preserves FDA terminology without turning a general endpoint framework into an automatic checklist.
- An endpoint-by-endpoint evidence matrix separating new testing, existing device-specific evidence, chemistry/toxicology support, documented rationale, unresolved applicability, and gaps.
- A report-quality and applicability record linked to complete reports, test articles, methods, deviations, acceptance criteria, results, limitations, and the current device.
- A final-finished-device comparison that makes formulation, processing, sterilization, geometry, surface, additives, joining agents, cleaning agents, and residues visible.
- A controlled eSTAR and attachment map using the submission's own current template and FDA route instructions rather than a hard-coded future form.
- Separate records for Traditional 510(k), Special 510(k), Technical Screening, Interactive Review, and Additional Information so their rules and clocks are not conflated.
- A reviewer-ready draft section and action/decision handoff with exact evidence locators, limitations, source dates, named reviewers, and approval status.

SCOPE This resource structures preparation and review. It does not select tests, determine endpoint applicability, establish toxicological acceptability or biological safety, decide 510(k) eligibility, constitute an FDA submission, or predict FDA acceptance. Device-specific conclusions and submission decisions require qualified review.

The working sequence

Step	Action	Output
1	Freeze the exact device, submission objective, predicate strategy, indications, variants, contact profile, and final finished state.	Controlled submission scope
2	Confirm the current FDA device category, contact nature, duration, product-specific guidance, special controls, and recognized-standard records.	FDA framework record
3	Map every biological decision area to an evidence route and current-device applicability state.	Endpoint evidence matrix
4	Register complete reports and extract identity, method, article, deviations, results, acceptance criteria, limitations, and signatures.	Evidence and report register
5	Compare each test article or prior device with the final finished subject device and record every relevant difference.	Representativeness record
6	Link chemistry and toxicology only to the questions they can support and preserve unresolved local or device-specific effects.	Chemistry/TRA bridge
7	Build the FDA section, eSTAR response locations, and attachment map from the controlled evidence set.	Draft section and attachment map
8	Run cross-file QA and hand the candidate to named biological-safety, toxicology, regulatory, and submission reviewers.	Qualified-review package



Decision dashboard

Fail-closed status view — this is not a compliance or safety score | v3.0-rc1

CONTROL COUNTS

Assessment items	12
Incomplete controls	20
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

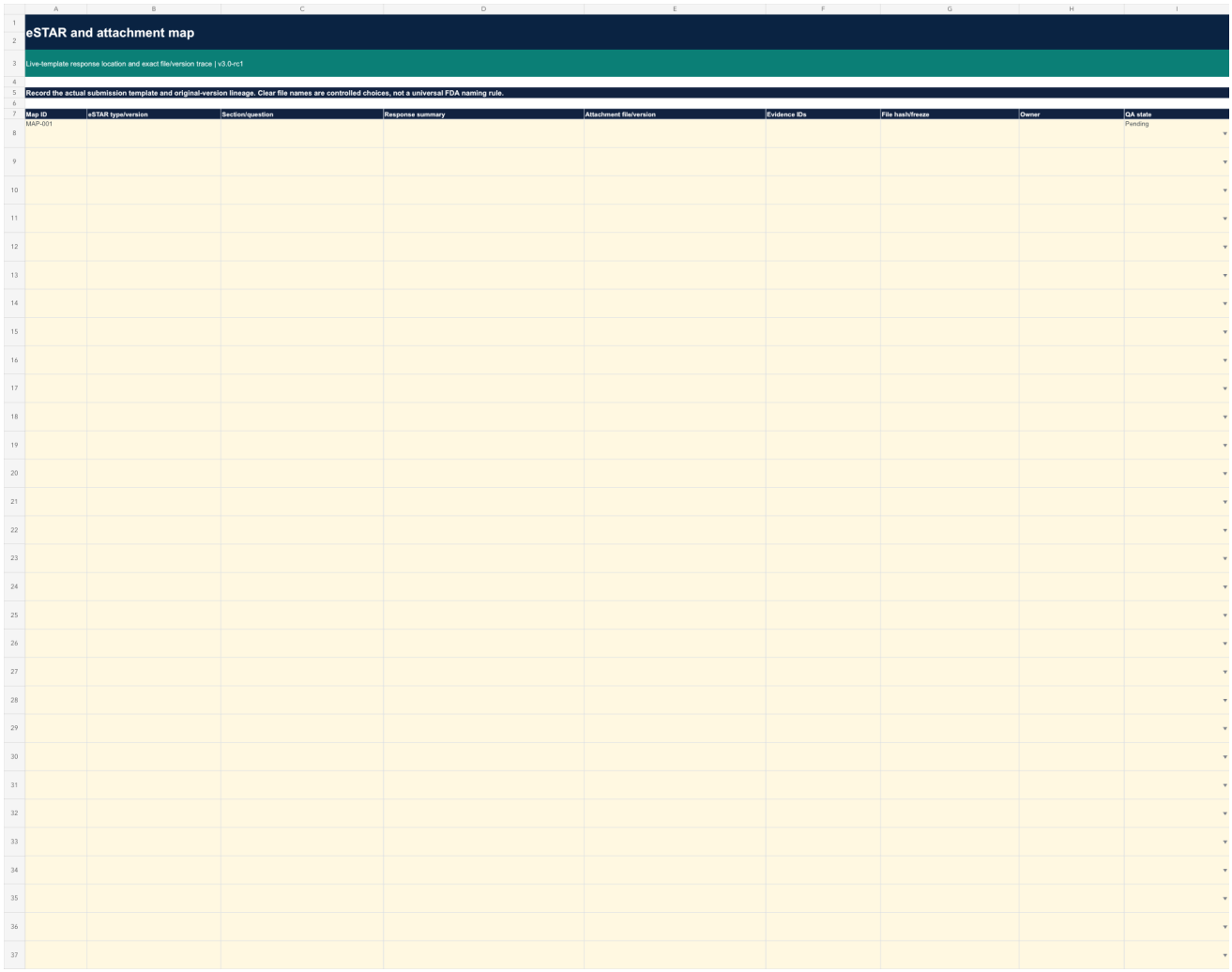
OVERALL CONTROL STATUS

ASSESSMENT INCOMPLETE

INTERPRETATION

The dashboard enforces sequencing and escalation. It does not decide endpoint applicability, evidence adequacy, test selection, toxicological acceptability, biological safety, conformity, or regulator acceptance. Resolve each row and preserve the supporting evidence and named reviewer decision.

Decision dashboard — fail-closed control view from the current candidate build



eSTAR and attachment map

Live-template response location and exact file/version trace | v3.0-rc1

Record the actual submission template and original-version lineage. Clear file names are controlled choices, not a universal FDA naming rule.

Map ID	eSTAR type/version	Section/question	Response summary	Attachment file/version	Evidence IDs	File hash/freeze	Owner	QA state
MAP-001								Pending

eSTAR and attachment map — current-template response and file trace

WHAT THE PREVIEW DEMONSTRATES The product controls submission identity, evidence, report review, attachment mapping, review communications, sources, and qualified decisions. It does not supply a prewritten FDA conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Run the safe workflow in the intended order and identify stop conditions.	The team knows which record to use, who owns each step, and when to escalate.
Implementation Guide PDF	Understand FDA route, device, evidence, report, eSTAR, and review boundaries.	The selected approach and its limitations can be explained without generic claims.
Editable Working Templates DOCX	Draft controlled scope, evidence, comparison, response, decision, and handoff records.	All response areas contain device-specific content and open items are resolved or owned.
Operational Workbook XLSX	Control sources, reports, status, formulas, red flags, actions, and qualified decisions.	No incomplete control or unowned stop condition remains and named reviewers are recorded.
Source Status and Release Notes PDF	Verify FDA source status, recognition extent, transitions, and recheck triggers.	The source register matches the exact authorities used for the candidate.
README, responsible-use terms, manifest, and checksums	Orient the recipient, preserve integrity, and control authorized use.	Identity, version, files, hashes, support route, and use boundaries agree.

What is deliberately not promised

- No automated selection of tests, endpoint applicability, 510(k) route, or predicate strategy.
- No biological-safety, toxicological-acceptability, substantial-equivalence, compliance, or FDA-acceptance determination.
- No reproduction of ISO standards or replacement for lawfully obtained standards, current FDA guidance, device-specific controls, and the live eSTAR.
- No guarantee that legacy or comparator evidence applies to a changed device, formulation, process, sterilization, surface, or use.
- This preview does not provide legal, privacy, refund, tax, processor, regulatory, scientific, or individualized commercial advice; the applicable order and terms control.

AVAILABILITY Current customer edition — available by request. Online checkout, payment collection, public buyer-file download, and automatic delivery are not enabled.