

Covers manufacturers of finished medical devices, contract manufacturers, and component and software suppliers to device makers — Class I, II, and III, including implants, single-use disposables, diagnostics, and connected devices. Complete with ACORD 125/126. Attach a product list with FDA class and clearance numbers, the most recent FDA inspection results, and key OEM or supply agreements.

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APPLICANT / BUSINESS INFORMATION

LEGAL BUSINESS NAME	DBA	FEIN	YEARS IN BUSINESS
PLANT ADDRESS	CITY / STATE / ZIP	WEBSITE	
Entity type:			
☐ Sole proprietor ☐ Partnership ☐ LLC ☐ Corporation ☐ Other			
PRIMARY CONTACT / TITLE	PHONE	EMAIL	
FDA ESTABLISHMENT REGISTRATION NO.	ISO 13485 CERTIFIER / EXPIRATION	LAST FDA INSPECTION / OUTCOME	

2

OPERATIONS

DESCRIPTION OF THE BUSINESS (DEVICES OR COMPONENTS MADE, CUSTOMERS, PLANTS, PROCESSES)

Applicant's role (check all):

☐ Finished device maker (own label) ☐ Contract manufacturer for OEMs ☐ Component supplier ☐ Specification developer (outsources making)

☐ Software / app developer ☐ Sterilizer / reprocessor

DEVICE OR COMPONENT	FDA CLASS	% OF SALES

Device characteristics (check all):

☐ Implanted > 30 days ☐ Life-sustaining / life-supporting ☐ Sterile ☐ Connected / software-driven ☐ Contains drug or biologic

☐ Used in the home ☐ Pediatric use ☐ Sold outside the U.S.

Size and volume:

Devices / SKUs Units shipped per year Plant locations OEM customers Critical suppliers

3

EXPOSURE & RISK QUESTIONS — DESIGN, QUALITY & REGULATORY

Since February 2, 2026, FDA's quality rule incorporates ISO 13485 and lets inspectors review management review and supplier audit reports. A degrading foam component led Philips to recall 15 million devices and pay about \$1.1 billion in injury settlements.

3-1 Does the applicant control the design of its devices, with design history files and risk analysis (ISO 14971)?

☐ Yes ☐ No

IF YES, EXPLAIN

3-2 Are materials that contact patients or the airway tested for biocompatibility and long-term degradation?

☐ Yes ☐ No

IF YES, EXPLAIN

3-3	Are critical suppliers qualified, audited, and controlled by written quality agreements?	☐ Yes ☐ No
IF YES, EXPLAIN		
3-4	Has the applicant received an FDA Form 483, warning letter, or import alert in the last 5 years?	☐ Yes ☐ No
IF YES, EXPLAIN		
3-5	Are complaints investigated and deaths or serious injuries reported to FDA within required timeframes?	☐ Yes ☐ No
IF YES, EXPLAIN		
3-6	Are any devices marketed for uses not covered by their clearance or approval?	☐ Yes ☐ No
IF YES, EXPLAIN		
3-7	Do connected devices have a cybersecurity plan, software bill of materials, and patch process?	☐ Yes ☐ No
IF YES, EXPLAIN		
3-8	Is the applicant conducting or sponsoring any clinical trials or human studies?	☐ Yes ☐ No
IF YES, EXPLAIN		

4 EXPOSURE & RISK QUESTIONS — CONTRACTS, RECALL & MANUFACTURING

4-1	Do OEM contracts require the applicant to pay recall costs, indemnify the OEM, or carry specific limits?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-2	Does the applicant make components without knowing the finished device they go into?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-3	Can every lot or serial number be traced to customers, with UDI where required?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-4	Has any device or component been recalled, corrected, or removed in the last 10 years?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-5	Are sterilization (ethylene oxide, gamma, steam) processes validated, and is any done in house?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-6	Are clean rooms, process validations, and equipment calibration documented and current?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-7	Are any devices or components imported, or made by contract manufacturers outside the U.S.?	☐ Yes ☐ No
IF YES, EXPLAIN		

5 PAYROLL, SALES & REVENUE

TOTAL ANNUAL PAYROLL (\$, ILLUSTRATIVE)	NUMBER OF EMPLOYEES	R&D / ENGINEERING STAFF
PROJECTED ANNUAL GROSS SALES (\$, ILLUSTRATIVE)	PRIOR YEAR SALES (\$, ILLUSTRATIVE)	CLASS III / IMPLANT SALES (\$, ILLUSTRATIVE)

6 PRIOR INSURANCE & LOSS HISTORY

Attach currently-valued loss runs for the last 10 years.

CURRENT PRODUCTS CARRIER

PRODUCTS LIMITS / RETRO DATE

RECALL LIMIT (IF ANY)

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6-1 Has any carrier declined, cancelled, or non-renewed coverage for this business in the last 5 years?

☐ Yes ☐ No

IF YES, EXPLAIN

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6-2 Does the current policy exclude implants, specific devices, or materials?

☐ Yes ☐ No

IF YES, EXPLAIN

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DATE OF LOSS	DESCRIPTION	TOTAL INCURRED (\$, ILLUSTRATIVE)	OPEN / CLOSED

6-3 Is the applicant aware of any incident, complaint, or circumstance not yet resulting in a claim that could reasonably give rise to one?

☐ Yes ☐ No

IF YES, EXPLAIN

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7 RISK MANAGEMENT & SAFETY

7-1 Is there a written recall plan, tested with a mock recall in the last 2 years?

☐ Yes ☐ No

IF YES, EXPLAIN

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7-2 Are labeling, instructions for use, and promotional materials reviewed by regulatory staff before release?

☐ Yes ☐ No

IF YES, EXPLAIN

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7-3 Are quality records kept for the life of the device plus at least 2 years?

☐ Yes ☐ No

IF YES, EXPLAIN

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8 SIGNATURE & FRAUD WARNING

The undersigned declares that the statements and answers given in this supplemental are true, complete and correct to the best of their knowledge, and that no material fact has been withheld or misstated. The applicant agrees that this supplemental, together with all ACORD applications and attachments, forms the basis of any submission to insurers and may be relied upon by them. Signing this supplemental does not bind coverage. This supplemental is an intake document prepared by Cory Washington & Co. LLC to support carrier submission; it does not itself provide coverage.

FRAUD NOTICE: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. (State-specific fraud warnings apply; see state amendatory notice.)

APPLICANT / AUTHORIZED SIGNATURE (TYPE FULL NAME)

TITLE

DATE

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PRODUCER — CORY WASHINGTON & CO. LLC

PRODUCER SIGNATURE (TYPE FULL NAME)

DATE

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