MEDICAL DEVICE CORPORATE CLIENT INTAKE QUESTIONNAIRE:

REPORTING CLOCKS RUN IN DAYS. Device-related deaths, serious injuries, and malfunctions carry adverse event reporting deadlines, and corrections and removals must be reported shortly after they begin. Do not include patient data or unpublished clinical information on this form — we will arrange a secure channel after a confidentiality agreement is in place.

CONFIDENTIAL. This questionnaire covers corporate legal work and capital markets advisory for medical device businesses — diagnostic, monitoring, imaging, surgical, implantable, therapeutic, and healthcare IT products — including manufacturers, specification developers, contract manufacturers, importers, and distributors. Complete the sections that apply. If a question does not apply, write "N/A."

NAME OF THE CLIENT:

[__] Legal Entity Name: _____

DBA / brand or product names: _____ Year founded: _____

Entity type:

- [__] Corporation
- [__] LLC
- [__] Partnership
- [__] Public company
- [__] Subsidiary of a parent
- [__] Foreign parent or operations

State of formation: _____ EIN (last 4): _____

Establishment registration no.: _____ Syndicate Plan Member ID: _____

Contact person & title: _____

Address: _____

City: _____ County: _____ State: _____ Zip: _____

Phone: _____ Email: _____

Annual revenue: $ _____ Employees: _____

PART 1 — YOUR BUSINESS & PRODUCTS

1.1 Product categories:

- [__] Diagnostic devices
- [__] Monitoring & telemetry
- [__] Imaging (CT, MRI, radiographic)
- [__] Surgical instruments & lasers
- [__] Implantable products
- [__] Cardiac devices (pacemakers, defibrillators)
- [__] Anesthesia & bypass equipment
- [__] Catheters & access devices
- [__] Dialysis equipment
- [__] Endoscopes
- [__] Ophthalmic devices
- [__] Neonatal & infant care equipment
- [__] Sterilization & processing equipment
- [__] Electrical stimulation & therapeutic devices
- [__] Aesthetic & cosmetic devices
- [__] Healthcare IT & device software

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1.2 Your role:

[__] Manufacturer
[__] Contract manufacturer
[__] Distributor / dealer
[__] Service & repair provider
[__] Specification developer
[__] Importer
[__] Repackager or relabeler

1.3 Describe your products and current stage: _____

_____

_____

PART 2 — SERVICES NEEDED

Entity, Governance & Filings:

[__] Formation or incorporation
[__] Operating agreement / bylaws
[__] Annual reports & business filings
[__] International incorporation
[__] Entity conversion / restructuring
[__] Corporate resolutions
[__] Foreign qualification
[__] Business licenses & permits

Regulatory & Quality:

[__] Device classification & pathway analysis
[__] Establishment registration & device listing
[__] Unique device identification & labeling
[__] Adverse event reporting procedures
[__] Inspection response & warning letters
[__] Premarket submissions & responses
[__] Quality system & design controls
[__] Instructions for use & labeling review
[__] Recalls, corrections & removals
[__] Software & cybersecurity requirements

Clinical, Reimbursement & Compliance:

[__] Clinical study agreements & site contracts
[__] Institutional review & informed consent documents
[__] Anti-kickback & referral analysis
[__] Transparency & payment reporting
[__] Off-label communication review
[__] Investigational device requirements
[__] Coverage, coding & reimbursement strategy
[__] Physician consulting & royalty arrangements
[__] Sales & marketing compliance
[__] Compliance program development

Contracts, Supply Chain & Distribution:

[__] Supplier & component agreements
[__] Contract manufacturing & sterilization agreements
[__] Quality agreements
[__] Sales representative agreements
[__] Service, warranty & maintenance terms
[__] Distributor & dealer agreements
[__] Group purchasing & hospital contracts
[__] Software licenses & hosting agreements

[__] Supply chain disputes
[__] Non-disclosure agreements

IP, Trade & International:

[__] Patents & freedom to operate
[__] Trade secrets & design files
[__] Trademarks & brand protection
[__] Licensing & technology transfer
[__] IP infringement claims
[__] Import & export requirements
[__] International registrations & conformity marking
[__] Tariffs & customs classification

Capital Markets & Finance:

[__] Capital markets consultation
[__] Private placement (Reg D / Reg A)
[__] Venture or growth equity documents
[__] Secured lending & equipment finance
[__] Exchange listing (OTC, Nasdaq, NYSE, international)
[__] Securities & blue sky compliance
[__] Mergers, acquisitions & product line sales
[__] Investor agreements & cap table
[__] Restructuring or bankruptcy

2.1 Describe your most urgent matter and objective: _____

_____

_____

2.2 Deadline (submission, response, launch, closing): _____

PART 3 — PRODUCTS & REGULATORY STATUS

Product	Class	Pathway (510(k), De Novo, PMA, exempt)	Clearance / Approval No.	Status

3.1 Is the classification and regulatory pathway confirmed for each product? [__] Yes [__] No

3.2 Are establishment registration and device listing current? [__] Yes [__] No

3.3 Is a new product, modification, or labeling change planned? [__] Yes [__] No

Changes to design, materials, manufacturing, or intended use can require a new premarket submission. Document the change assessment before launch.

3.4 Does any product include software, connectivity, or AI features? [__] Yes [__] No

3.5 Are unique device identifiers assigned and data submitted? [__] Yes [__] No

Syndicate Subscription Legal Plans

PART 4 — QUALITY SYSTEM, COMPLAINTS & RECALLS

Program Area	In Place	Needs Update	Missing
Quality management system & procedures	[__]	[__]	[__]
Design controls & design history files	[__]	[__]	[__]
Supplier controls & incoming inspection	[__]	[__]	[__]
Complaint handling & investigation	[__]	[__]	[__]
Adverse event reporting procedures	[__]	[__]	[__]
Corrections, removals & recall procedures	[__]	[__]	[__]
Corrective and preventive action system	[__]	[__]	[__]
Sterilization & validation records	[__]	[__]	[__]
Labeling control & change management	[__]	[__]	[__]
Cybersecurity & postmarket monitoring	[__]	[__]	[__]

4.1 Inspection, observations, or warning letter in the last 3 years? [__] Yes [__] No

4.2 Have you filed adverse event reports, or are any decisions pending? [__] Yes [__] No

4.3 Has a recall, correction, removal, or field safety notice occurred? [__] Yes [__] No

4.4 Are complaint trends or malfunction rates being tracked and escalated? [__] Yes [__] No

4.5 Are there product liability claims or injury reports pending? [__] Yes [__] No

If yes, explain: _____

_____

PART 5 — CLINICAL, REIMBURSEMENT & FRAUD AND ABUSE

5.1 Are clinical studies underway or planned? [__] Yes [__] No

Sites, sponsor role & study status: _____

5.2 Are investigational device requirements and study approvals in place? [__] Yes [__] No

5.3 Do you pay physicians as consultants, speakers, advisors, or inventors? [__] Yes [__] No

Payments to physicians and teaching hospitals generally must be reported, and arrangements tied to purchasing or referrals raise anti-kickback exposure.

5.4 Do you provide product samples, evaluations, loaners, or training support? [__] Yes [__] No

5.5 Do you assist customers with coding, coverage, or billing? [__] Yes [__] No

5.6 Do sales incentives reward volume from specific accounts or providers? [__] Yes [__] No

PART 6 — SUPPLY CHAIN, DISTRIBUTION & IP

Key Supplier, Manufacturer or Distributor	Role	Country	Annual Value $	Quality Agreement?

6.1 Do you rely on single-source components, sterilizers, or contract manufacturers? [__] Yes [__] No

6.2 Are quality agreements in place with suppliers and contract manufacturers? [__] Yes [__] No

6.3 Do distributor agreements address regulatory and complaint duties? [__] Yes [__] No

6.4 Do you own patents, and has freedom to operate been analyzed? [__] Yes [__] No

6.5 Do employees, consultants, and contract developers assign IP in writing? [__] Yes [__] No

6.6 Do you sell abroad, with registrations and marks current? [__] Yes [__] No

PART 7 — FINANCE, PEOPLE & DISPUTES

Existing Debt / Investment	Lender or Investor	Amount $	Terms	Secured By

7.1 Capital sought: $ _____ Purpose: _____

7.2 Capital strategy:

[__] Product development & clinical studies [__] Regulatory submissions & launch

[__] Manufacturing scale-up [__] Working capital

[__] Growth equity or venture capital [__] Public offering or listing

[__] Sale of the company or product line [__] Not sure — need advice

7.3 Employees: _____ Contractors: _____ States / countries with workers: _____

7.4 Is immigration sponsorship needed for engineers or regulatory personnel? [__] Yes [__] No

7.5 Current disputes:

[__] Product liability claim [__] Supplier or manufacturing dispute

[__] Distributor or sales dispute [__] IP infringement

[__] Regulatory enforcement [__] Reimbursement dispute

[__] Employment claim [__] Collections

[__] None

PART 8 — DOCUMENTS & CERTIFICATION

8.1 Is a non-disclosure agreement required before documents are shared? [__] Yes [__] No

Please provide the following, if applicable. Check each item available. Do not include patient identifiers or unpublished clinical data.

[__] Formation & governance documents [__] Ownership / cap table

[__] Financial statements & projections [__] Clearance or approval letters

[__] Labeling & instructions for use [__] Quality system procedures & audit reports

[__] Supplier & manufacturing agreements
[__] Distributor & sales agreements
[__] Agency correspondence & inspection records
[__] Patent filings & IP assignments

Certification:

I declare that the information provided in this questionnaire is true, correct, and complete to the best of my knowledge, that I am authorized to provide it on behalf of the business named above, and that it does not include patient identifiers. I understand this information is provided to Syndicate Subscription Legal Plans in confidence for the purpose of evaluating and scoping this engagement.

Signed and dated this ____ day of _____, 20___

Signature: _____

Print Name: _____

Title: _____

Please Print and Email to STEVE@STEVEMUELLERLEGAL.COM, or save this document as a PDF and email to STEVE@STEVEMUELLERLEGAL.COM,
Your information will be reviewed within one hour.