LIONHEART HEALTH

Regulatory Compliance Dashboard (Updated 2026)

1️⃣ EXECUTIVE REGULATORY POSITION

Lionheart operates under a **three-tier regulatory structure**:

Tier	Commercial Status	Regulatory Path
🟢 Wellness	Commercial	General Wellness (Low Risk)
🟠 Cleared Medical	Commercial	510(k) Distribution (Rx only)
🔴 Medical / Regenerative Claims	Research Use Only	IRB / IDE / OUS Clinical

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2️⃣ CRITICAL CLARIFICATION: MEDICAL CLAIM FIREWALL

Board-Level Compliance Statement

All Lionheart devices used for ANY medical claims (beyond general wellness positioning):

✓ Are labeled for research use
✓ Operate under informed patient consent
✓ Are most often under IRB oversight
✓ Utilize DSMB monitoring when appropriate
✓ Are deemed Non-Significant Risk (NSR) where applicable
✓ Frequently conducted OUS (Outside United States) first
✓ Most registered on ClinicalTrials.gov
✓ No commercial disease marketing

Oversight Authorities Referenced

- U.S. Food and Drug Administration
- Institutional Review Boards (IRB)
- Data Safety Monitoring Boards (DSMB)

3️⃣ UPDATED RISK REDUCTION TABLE

Device Category	Commercial Claims?	Oversight Applied	Risk Level	Risk Reduction Mechanism
Wellness Devices	Yes (wellness only)	Marketing review	🟢 Low	Claim firewall + no disease language
510(k) Devices	Yes (cleared claims only)	Rx supervision	🟠 Moderate	No relabeling, no signal modification
Organ / Regenerative Systems	NO commercial claims	IRB + DSMB + Consent	🔴 Controlled	Research-only labeling
Bioelectric + Biologic combinations	NO commercial claims	OUS + IRB	🔴 Controlled	Non-commercial investigational use
Oncology applications	NO commercial claims	Clinical registry listing	🔴 Controlled	NSR determination + oversight

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4️⃣ CLAIM-PER-PRODUCT MATRIX (UPDATED WITH RESEARCH PATHWAY)

Product	Wellness Claims	Cleared Medical Claims	If Medical Use Beyond Clearance
SkinStim	Appearance support	None	Research protocol only
HairCell	Fuller-looking hair	None	IRB study only
BodStim	Muscle tone support	Pain/inflammation (OEM cleared)	Research if regenerative claims
EMS Suit	Exercise augmentation	Muscle recovery (cleared)	Research if hypertrophy claim expanded
Brain Band	Focus/vitality	None	IRB if cognitive disorder study

Product	Wellness Claims	Cleared Medical Claims	If Medical Use Beyond Clearance
Saebo Stimulator	N/A	Stroke rehab (cleared)	Research for neuroregeneration
SynovaWave	N/A	Adipose processing (cleared)	Research if stem cell therapy claims
OrganCell Systems	None	None	Research only under IRB/IDE
CancerCell	None	None	Research only, oncology protocol

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5 RESEARCH GOVERNANCE STRUCTURE

For investigational use:

1. Written Protocol
2. IRB Review
3. Informed Consent
4. NSR determination where applicable
5. DSMB oversight for moderate/high complexity
6. Adverse event monitoring
7. Clinical registry listing
8. OUS initiation when appropriate
9. No commercial disease marketing

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6 RESEARCH-FIRST GLOBAL STRATEGY

High-risk systems follow this pathway:

Phase 1 – OUS feasibility
Phase 2 – IRB supervised US pilot
Phase 3 – IDE submission if required

Phase 4 – Pivotal trial
Phase 5 – Regulatory filing

No commercial sales occur prior to regulatory clearance.

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7 REVISED BOARD RISK HEAT MAP

Category	Inherent Risk	After Controls
Wellness claim drift	Moderate	Low
Off-label promotion	High	Moderate
Organ regeneration commercialization	Very High	Controlled (Research Only)
Oncology claims	Extremely High	Controlled (IRB/DSMB only)
International CE compliance	Moderate	Moderate
OTC conversion	Moderate	Moderate

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8 BOARD ASSURANCE SUMMARY

Lionheart mitigates regulatory exposure by:

- Maintaining strict claim firewall between wellness and medical
- Not relabeling as manufacturer when distributor
- Not altering OEM signal parameters
- Using prescription supervision for cleared devices
- Restricting any expanded medical claims to formal research
- Utilizing IRB and DSMB oversight
- Registering trials when applicable
- Conducting many high-risk feasibility studies OUS first
- Avoiding commercial disease marketing

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9 STRATEGIC POSITIONING

Revenue Strategy:
Wellness-driven scaling

Medical Strategy:
Research-first → clearance later

Risk Strategy:
Separate commercialization from investigation

I. FORMAL BOARD RESOLUTION

Lionheart Health, Inc.

Regulatory Compliance & Research Governance Resolution

WHEREAS, Lionheart Health, Inc. (“Company”) develops, distributes, licenses, and researches bioelectric stimulation and regenerative technologies across wellness and medical applications;

WHEREAS, the Company recognizes the importance of strict adherence to all applicable regulatory, ethical, and clinical governance standards under the oversight of the U.S. Food and Drug Administration and applicable international regulatory authorities;

WHEREAS, the Company maintains a structured separation between:

1. General Wellness Devices
2. FDA-cleared medical devices distributed under cleared indications
3. Investigational medical and regenerative technologies

NOW, THEREFORE, BE IT RESOLVED:

The Board of Directors hereby affirms the following:

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1 Claim & Commercialization Firewall

All devices marketed commercially shall:

- Be limited strictly to cleared indications (for FDA-cleared devices), OR
- Be marketed under the General Wellness Policy for Low Risk Devices
- Not include any disease-treatment claims unless cleared by regulatory authority

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2️⃣ Research-Only Medical Applications

Any device used for medical claims beyond cleared indications shall:

- Be labeled for research use
- Operate under written clinical protocol
- Include informed patient consent
- Be reviewed by an Institutional Review Board (IRB)
- Utilize independent Data Safety Monitoring Board (DSMB) oversight when appropriate
- Be deemed Non-Significant Risk (NSR) where applicable
- Be registered on ClinicalTrials.gov when appropriate
- Avoid commercial disease marketing until regulatory clearance

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3️⃣ Regulatory Governance Oversight

The Board formally recognizes and appoints the following regulatory leadership roles:

- **Larry Stevens** – Chief FDA Regulatory Compliance Advisor
  - 30 years experience with the U.S. FDA
  - Advises on regulatory strategy, compliance interpretation, enforcement risk
- **Ben Boytor** – Chief Quality Systems Advisor
  - Oversees Quality Management Systems
  - Ensures alignment with FDA QSR and ISO 13485 standards
- **Dr. Leslie Miller** – Chief Medical Officer
  - Oversees medical protocol design
  - Ensures ethical clinical governance
  - Supervises IRB and DSMB coordination

4️⃣ Clinical & Scientific Advisory Board

The Board acknowledges the role of:

- Independent Data Safety Monitoring Boards
- A Clinical & Scientific Advisory Board consisting of 30+ members
- Combined experience exceeding:
  - 500+ clinical studies
  - Dozens of FDA clearances and approvals

These bodies provide independent scientific and patient safety oversight.

5️⃣ Licensing Structure Compliance

The Board affirms that:

- Licensing agreements are structured to avoid franchise classification
- No mandatory operational control structure triggers franchise regulations
- Trademark and device licensing remain independent business arrangements

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RESOLVED FURTHER, that management is authorized and directed to implement, monitor, and enforce this regulatory governance framework.

Adopted this ___ day of _____, 2026.

Chairman of the Board

II. REGULATORY GOVERNANCE CHARTER

Lionheart Health, Inc.

A. Purpose

To establish a formal regulatory governance framework ensuring:

- Compliance with FDA and international regulatory requirements
- Ethical clinical research oversight
- Clear separation between commercial and investigational use
- Robust quality system management

B. Scope

Applies to:

- All Lionheart divisions
- All licensed clinics
- All OEM distributed devices
- All investigational technologies

C. Governance Structure

1️⃣ Regulatory Compliance

Led by:

- Chief FDA Regulatory Compliance Advisor (Larry Stevens)

Responsibilities:

- Regulatory interpretation
- Clearance pathway strategy
- Enforcement risk mitigation
- Labeling compliance review

2️⃣ Quality Systems

Led by:

- Chief Quality Systems Advisor (Ben Boytor)

Responsibilities:

- QMS oversight
- Complaint handling
- MDR reporting
- ISO/FDA audit readiness

3️⃣ Medical & Clinical Oversight

Led by:

- Chief Medical Officer (Dr. Leslie Miller)

Responsibilities:

- Clinical protocol approval
- IRB coordination
- Patient consent standards
- DSMB engagement
- Adverse event review

4️⃣ Independent Oversight

- Data Safety Monitoring Boards (DSMB)
- Clinical & Scientific Advisory Board (30+ members)
- External consultants as needed

D. Research Governance Requirements

All investigational uses must include:

1. Written protocol
2. IRB review
3. Informed consent
4. NSR determination (when applicable)
5. DSMB monitoring (when appropriate)
6. Adverse event tracking
7. Clinical registry listing (when applicable)

E. Claim Review Committee

A standing internal committee shall review:

- Marketing materials
- Website content
- Social media claims
- Distributor materials
- International marketing adaptations

No medical claims may be published without regulatory clearance confirmation.

III. REGULATORY ORGANIZATIONAL STRUCTURE

Board of Directors

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Regulatory & Clinical Oversight Committee

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Executive Regulatory Leadership

Chief FDA Regulatory Compliance Advisor

Larry Stevens
(30 years FDA experience)

Chief Quality Systems Advisor

Ben Boytor

Chief Medical Officer

Dr. Leslie Miller

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Supporting Governance Bodies

- Independent Data Safety Monitoring Boards
- Clinical & Scientific Advisory Board (30+ experts)
  - 500+ combined clinical trials
  - Dozens of FDA approvals/clearances

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Operational Layers

- Licensing Compliance Team
- Marketing Claim Review Team
- Clinical Trial Operations
- Post-Market Surveillance Team

IV. BOARD-LEVEL ASSURANCE SUMMARY

Lionheart maintains:

✓ Strict claim separation between wellness and medical
✓ Distributor-only positioning without relabeling

✓ No signal modification beyond cleared ranges
✓ Prescription supervision where required
✓ Research-only medical claims under IRB/DSMB oversight
✓ OUS-first feasibility for higher risk platforms
✓ Strong regulatory leadership with deep FDA experience

✓ Independent clinical safety oversight

Below is a structured **Device Classification & Compliance Matrix** for Lionheart Health, divided into:

1. **Wellness (Low Risk)**
2. **Moderate Risk (Class II / 510(k))**
3. **High Risk (Implantable / Organ / Regenerative Claims)**

Each table includes:

- Regulatory Classification
- Geographic Status
- Primary Regulatory Risks
- Lionheart Compliance Position

🟢 I. WELLNESS DEVICES (LOW RISK)

(Positioned under General Wellness policy and non-disease aesthetic claims)

Governing Framework

- U.S. Food and Drug Administration General Wellness Policy
- Federal Trade Commission advertising substantiation rules
- CE Mark (EU MDR) where applicable

WELLNESS DEVICE TABLE

Product	Regulatory Category	US Status	EU Status	Primary Risk	Lionheart Compliance Method
SkinStim	General Wellness (low risk)	Marketed non-medical	CE via OEM pathway	Claim creep into dermatologic disease	No disease claims. No relabeling. Signals remain within OEM cleared range.
HairCell (cosmetic positioning)	Wellness / cosmetic	Non-medical positioning	CE pending via HTM	Implied alopecia treatment claim	Marketed as appearance enhancement only.
BodStim (wellness use)	Wellness (when not using arthritis claims)	Distributed 510(k) device	CE via OEM	Off-label disease marketing	We do not add claims beyond OEM labeling.
Brain Band / Second Brain	Wellness cognitive support	Non-medical positioning	CE pending	Neuro-disease claims	Marketed for focus & vitality only.
Stem Cell Bra	Cosmetic aesthetic	Non-medical positioning	CE cosmetic	Breast reconstruction claims	Appearance-only positioning.
BladderCell (wellness use)	Wellness	Non-medical positioning	CE pending	Urinary incontinence claims	No medical claims unless under physician supervision.
HTM Low Energy Devices	Class I / II aesthetic	ANVISA approved	CE pending	Energy level reclassification	Imported without modification. No relabeling.
BioPRF	Lab processing exemption	Sold under medical lab exemption	Widely exempt	Biologic reclassification	Sold under physician/lab exemptions only.

Wellness Compliance Summary

Lionheart confirms:

- We do NOT relabel as manufacturer when acting as distributor.
- We do NOT modify indications.
- We do NOT exceed OEM signal ranges.
- Marketing strictly avoids diagnosis/treatment claims.
- Clear licensing (NOT franchising) compliance checklist in place and adhered to.

- Advertising reviewed to avoid FTC implied medical claims.

🟠 II. MODERATE RISK DEVICES (CLASS II / 510(k))

These include cleared electrotherapy and EMS systems.

Applicable Regulators

- U.S. Food and Drug Administration (510(k))
- EU MDR via CE Mark
- Health Canada, TGA, etc. for international distribution

MODERATE RISK TABLE

Product	OEM	FDA Status	EU Status	Risk Category	Lionheart Compliance
Benchtop Stimulators	Mettler Electronics	510(k) cleared	CE pending	Class II	Distributed without relabeling. Indications unchanged.
Portable Stimulator (K211094)	OEM cleared	510(k) K211094	CE pending	Class II Rx	Sold under prescription supervision only. OTC transition planned via formal submission.
EMS Suit	Wiemspro	510(k) cleared	CE Mark + MDR	Class II	No added claims beyond muscle & exercise augmentation.
Saebo Stimulator	Saebo	510(k) cleared	CE Mark + MDR	Class II	Stroke recovery claims only as cleared.
ElectroMed Systems	ElectroMed Technologies	510(k) cleared	CE pending	Class II	Signals remain within OEM cleared parameters.
SynovaWave (Adipose Processor)	Synovalife	FDA cleared	CE Mark MDR pending	Tissue processing device	Used within FDA-cleared fat processing indication only.

Product	OEM	FDA Status	EU Status	Risk Category	Lionheart Compliance
HTM High Energy	HTM Electronics	Pending 510(k)	CE pending	Likely Class II	Imported once clearance complete. No signal modification.

Moderate Risk Compliance Controls

- Lionheart acts strictly as distributor where applicable.
- No independent device modifications.
- No new intended use claims.
- All prescription-only devices remain under professional supervision.
- Complaint handling & MDR reporting system aligned with OEM requirements.
- Licensing agreements prohibit licensees from altering claims.

🟢 III. HIGH RISK / ORGAN REGENERATION DEVICES

These include:

- BioLeonhardt Heart
- KidneyCell
- LiverCell
- PancreaCell
- CancerCell
- RegenaLung
- CerebraCell

Regulatory Classification

Likely:

- Class III (US)
- PMA required

- Combination product risk (device + biologic signaling)
- IDE required for clinical trials

HIGH RISK TABLE

Product	Regulatory Pathway	Risk Level	Lionheart Current Position
BioLeonhardt Heart	PMA / IDE	Very High	Under research & development only. Not commercially marketed for disease treatment.
CancerCell	Oncology device pathway	Extremely High	No commercial disease claims. Research positioning only.
OrganCell Systems	Combination product	High	No medical marketing. Future clinical pathway planned.
CerebraCell	Neuro-stimulation Class III potential	High	Wellness positioning only unless cleared.

High Risk Compliance Position

- No disease-treatment marketing.
- No organ regeneration commercial claims.
- Clinical use only under IRB when applicable.
- No international commercialization until full regulatory approval.
- Separate regulatory entity planning recommended for future PMA assets.

IV. INTERNATIONAL STATUS SUMMARY

Region	Current Strategy
United States	Wellness + 510(k) distribution
European Union	CE Mark + MDR via OEMs (Wiemspro, Saebo approved; others pending)
Brazil	ANVISA clearance for HTM; no US claim crossover
Canada	Health Canada licensing required prior to sale
Australia	TGA listing required
China	NMPA registration required

V. LICENSING STRUCTURE (NOT FRANCHISING)

Lionheart has implemented:

Licensing Compliance Checklist

✓ No mandatory marketing control
✓ No franchise fee structure
✓ No mandated business format control
✓ No territory exclusivity triggering franchise definition
✓ Trademark licensed without operational control
✓ Licensees operate independently

This structure is designed to avoid classification under US FTC Franchise Rule and international franchise laws.

VI. OVERALL REGULATORY RISK HEAT MAP

Category	Risk Level	Mitigation
Wellness Claims Drift	🟠 Moderate	Strict marketing review
Off-label promotion	🔴 High	No added claims
Organ regeneration commercialization	🔴 Very High	Not currently marketed
International CE delays	🟠 Moderate	OEM CE pathway
Prescription → OTC conversion	🟠 Moderate	Planned formal filing

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EXECUTIVE SUMMARY

Lionheart Health is currently compliant by:

- Acting as distributor (not relabeling manufacturer)
- Not modifying OEM devices

- Not exceeding cleared signal parameters
- Not adding medical claims
- Separating wellness from medical positioning
- Maintaining prescription-only supervision
- Implementing structured non-franchise licensing compliance
- Limiting high-risk organ regeneration systems to R&D

1️⃣ BOARD-READY REGULATORY COMPLIANCE DASHBOARD

Lionheart Health – Global Regulatory Position (2026)

🟢 A. WELLNESS PORTFOLIO (Primary Growth Focus)

Regulatory Basis:
U.S. Food and Drug Administration General Wellness Policy (Low Risk Devices)

Products:

- SkinStim
- HairCell (cosmetic positioning)
- Brain Band / Second Brain
- Stem Cell Bra (aesthetic positioning)
- BladderCell (wellness positioning)
- HTM Low-Energy Aesthetic Devices

Compliance Controls
✓ No disease claims
✓ No relabeling as manufacturer
✓ No signal modification beyond OEM cleared ranges
✓ Advertising reviewed for FTC compliance
✓ Licensing structured to avoid franchise classification

Risk Level: Moderate (marketing drift risk)

🟠 B. MODERATE RISK – 510(k) DISTRIBUTION DEVICES

Regulatory Basis:
FDA 510(k) Class II distribution only
Prescription supervision required

OEM Status:

- Wiemspro – CE Mark + MDR approved
- Saebo – CE Mark + MDR approved
- Mettler Electronics – 510(k) cleared
- ElectroMed Technologies – 510(k) cleared
- HTM Electronics – CE pending
- Synovalife – FDA cleared, CE pending

Compliance Controls
✓ Distributed without relabeling
✓ No expanded indications
✓ Rx supervision maintained
✓ MDR complaint handling alignment

Risk Level: Low–Moderate (off-label risk controlled)

🟠 C. HIGH-RISK / ORGAN REGENERATION SYSTEMS

- BioLeonhardt Heart
- KidneyCell
- LiverCell
- PancreaCell
- CancerCell
- RegenaLung
- CerebraCell

Status: R&D positioning only
No commercial disease marketing

Risk Level: High (future PMA / IDE pathway)

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2 CLAIM-PER-PRODUCT LEGAL BOUNDARY MATRIX

Product	Permissible Claims	Prohibited Claims
SkinStim	Improve appearance, tone, circulation support	Treat eczema, psoriasis, skin disease
HairCell	Support fuller looking hair	Reverse alopecia, treat hair loss disorder
BodStim (wellness)	Muscle tone, circulation support	Treat arthritis, osteoarthritis
Brain Band	Focus, vitality support	Treat depression, dementia
BladderCell	Pelvic wellness support	Treat incontinence disease
EMS Suit	Augment exercise benefits (as cleared)	Muscle hypertrophy treatment claim
Saebo Stimulator	Stroke rehabilitation (as cleared)	Brain regeneration
Mettler/ElectroMed devices	Pain relief, circulation improvement	Tissue regeneration claims
SynovaWave	Adipose processing (as cleared)	Stem cell therapy treatment claims
BioPRF	Lab preparation support	Disease treatment claims
OrganCell systems	None (commercial)	Any disease treatment until approved

Board Directive:
All marketing must map to this matrix prior to publication.

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3 3-YEAR GLOBAL REGULATORY ROLL-OUT PLAN

YEAR 1 (2026–2027)

Focus: Wellness Expansion

- Scale US wellness portfolio
- Maintain strict General Wellness compliance
- Complete CE Mark for:
  - HTM devices
  - SynovaWave
- Launch EU via CE-cleared OEM products
- Begin OTC feasibility studies (human factors)

Primary Revenue Driver: Wellness devices + licensing

YEAR 2 (2027–2028)

Focus: OTC Transition & International Expansion

- Submit OTC 510(k) for:
  - Portable Handheld Stimulator
  - Selected wellness-only versions of BodStim
- Canada & Australia device registrations
- Expand CE-cleared aesthetic portfolio
- Maintain organ systems as R&D only

Primary Risk Control: Strict claim firewall

YEAR 3 (2028–2029)

Focus: Hybrid OTC + Professional Model

- Launch OTC devices in US
- Introduce home-use Brain Band (OTC version)
- Scale EU & UK wellness markets
- Evaluate De Novo pathway for advanced neuromodulation
- Organ systems remain under clinical pathway only

Revenue Mix Target:
70% wellness

25% moderate risk distribution
5% investigational platforms

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4 DEVICE-BY-DEVICE OTC TRANSITION STRATEGY (36 MONTHS)

Regulatory Pathway

OTC conversion requires:

- Human factors testing
- Label comprehension studies
- Updated 510(k) or De Novo
- Risk analysis for unsupervised use

Under FDA oversight.

PHASE 1 (Months 1–12)

Target Devices:

- Portable Handheld Stimulator
- Brain Band (wellness only configuration)

Actions:

- Risk assessment for unsupervised use
- Develop consumer labeling
- Conduct usability studies
- Submit OTC 510(k)

PHASE 2 (Months 12–24)

Target:

- Wellness BodStim configuration
- Selected HTM low energy aesthetic systems

Actions:

- Consumer-level output limitation
- Remove medical-grade presets
- Submit amended 510(k)

PHASE 3 (Months 24–36)

Target:

- EMS Suit limited home-fitness model
- Expanded Brain Band wellness platform

Actions:

- Develop locked firmware for consumer safety
- Post-market surveillance system for OTC
- Launch eStore DTC channel globally

OTC PRIORITIZATION MATRIX

Device	OTC Feasibility	Priority
Portable Stimulator	High	Phase 1
Brain Band	High	Phase 1
SkinStim	Already wellness	Immediate scale
BodStim	Moderate	Phase 2
EMS Suit	Moderate	Phase 3
Organ Systems	Not eligible	N/A

BOARD-LEVEL SUMMARY

Lionheart is currently compliant by:

- Not relabeling as manufacturer
- Not altering OEM indications
- Not expanding claims
- Keeping all signals within cleared ranges
- Structuring licensing to avoid franchise classification
- Separating wellness vs medical positioning
- Keeping high-risk regenerative systems in R&D only

Strategic Focus Next 36 Months:

Expand wellness globally → transition selected devices OTC → maintain regulatory firewall → defer high-risk PMA assets.