# Lionheart Health – 510(k) Supported Device & Program Summary

## 1. Brain Band™ (Neuro-Wellness Platform)

**Base Device Support:**

- Flow Science bioelectric stimulation devices *(510(k)-cleared product line – partner supplied platform)*
- Nerve and Muscle Stimulator (including Saebo-aligned systems)
  → FDA 510(k): K211094

**FDA-Cleared Indications (Base Devices):**

- Muscle re-education
- Increased local blood circulation
- Relaxation of muscle spasms
- Prevention of disuse atrophy
- Maintenance/increase of range of motion
- Stroke rehabilitation support via neuromuscular stimulation

**Lionheart Brain Band™ Positioning:**

- Delivered via 510(k)-cleared stimulation platforms with **Lionheart proprietary signaling software**
- Focused on:
  - **Improving cerebral circulation**
  - **Reducing inflammation-related discomfort**
  - **Supporting brain wellness, recovery, and performance**

**Strategic Note:**

- Lionheart acts as **software + protocol layer + distributor**, not manufacturer of base cleared device
- Saebo collaboration strengthens **stroke recovery alignment within existing 510(k) scope**

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## 2. BodStim™ (Bioelectric EMS Suit Platform)

**Base Device Support:**

- Weimspro EMS system
  → FDA 510(k): K062616

**FDA-Cleared Indications:**

- Adjunctive treatment of:
  - Chronic, intractable pain
  - Post-surgical and post-traumatic acute pain
- Muscle stimulation / conditioning via EMS platform

**Lionheart BodStim™ Positioning:**

- Distributed EMS suits utilizing **FDA-cleared Weimspro platform**
- Enhanced with Lionheart signaling protocols for:
  - **Muscle activation and strengthening**
  - **Improved circulation**
  - **Inflammation modulation (comfort support framing)**
  - **Augmenting benefits of exercise**

**Use Context:**

- Core component of:
  - **Lionheart Klotho-Up™ Study**
  - Clinical and wellness protocols targeting muscle, metabolic, and systemic health

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# 3. Flow Science Joint Venture Model (Cross-Platform Strategy)

**Structure:**

- Lionheart **does not need new 510(k) clearance** for each application
- Instead:
  - Uses **existing FDA-cleared electrotherapy hardware**
  - Loads **Lionheart proprietary bioelectric signaling programs**
  - Distributes under physician supervision

**Regulatory Positioning:**

- Claims anchored to:
  - Circulation improvement
  - Muscle function support
  - Temporary pain relief
  - Wellness optimization

**Key Advantage:**

- Rapid scaling across multiple indications without duplicative regulatory pathways

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# 4. Saebo Collaboration (Stroke Recovery Integration)

**Base Device:**

- Saebo stimulation devices
- Supported by:
  - FDA 510(k): K211094

**Positioning:**

- Integration of Lionheart signaling into:
  - Stroke rehabilitation workflows
  - Neuromuscular re-education programs

**Clinical Alignment:**

- Fully consistent with cleared indications:
  - Muscle re-education
  - Circulation enhancement
  - Functional recovery support

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# 5. IRB-Approved Lionheart Klotho-Up™ Study (Clinical Scope Overlay)

**Regulatory Status:**

- Conducted under **Institutional Review Board (IRB) approval**

**Permitted Scope:**

- Bioelectric stimulation of:
  - **Any target tissue or organ system** as defined by study protocol
- Includes:
  - Brain (Brain Band™)
  - Muscle (BodStim™)
  - Organ systems (heart, kidney, etc.)

**Important Distinction:**

- IRB approval:
  - ☑ Permits **clinical research use and data collection**
  - ❌ Does **not equal FDA clearance for commercial disease claims**

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# Consolidated Positioning Statement (Recommended Use)

Lionheart Health delivers its Brain Band™ and BodStim™ platforms through partnerships with FDA 510(k)-cleared electrotherapy device manufacturers, including Flow Science systems, Saebo-aligned neuromuscular stimulators (K211094), and Weimspro EMS technology (K062616). These underlying devices are cleared for indications such as improving local circulation, muscle re-education, relaxation of muscle spasms, and pain management. Lionheart enhances these platforms through proprietary bioelectric signaling software and protocols. Certain applications are also deployed within IRB-approved clinical studies, including the Lionheart Klotho-Up™ Study, which permits multi-organ bioelectric stimulation for research purposes. Lionheart-branded programs themselves may not be independently FDA-cleared unless explicitly stated.