**Examples Demonstrating the Weighting System (With AI Chain of Thought)**

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**Introduction**

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Using our verified dataset of **149 FDA 510(k) submissions (119 unique applicants)**, we will demonstrate how the AI chain of thought led to improvements in our weighting system through two examples:

1. **High Likelihood Applicant**: An applicant with characteristics leading to a high overall likelihood score (approximately **96%**).
2. **Low Likelihood Applicant**: An applicant with characteristics resulting in a low overall likelihood score (approximately **32%**).

This approach highlights:

* Adjustments to the weighting system to differentiate low-likelihood cases accurately.
* The addition of **negative factors** for variables with low or no association to cadaveric tissue use.

**Example 1: High Likelihood Applicant**

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**Applicant Details**

* **Company Name:** OrthoInnovate Corp
* **Device Name:** AlloSpine Fusion System

**Applicant Characteristics**

**Internal Variables**

* **Advisory Committee:** Orthopedic (OR)
  + **Weight:** 0.85 (based on 56 OR submissions from 149 total).
  + **Rationale:** Orthopedic devices strongly correlate with cadaveric tissue.
* **Product Code:** MQV (Bone Void Filler Material)
  + **Weight:** 0.80 (9 verified submissions).
  + **Rationale:** Directly linked to tissue-related devices.
* **Device Name Keywords:** "Allograft," "Bone," "Fusion"
  + **Weights:**
    - "Allograft": 0.90
    - "Bone": 0.85
    - "Fusion": 0.80
  + **Average Weight:** (0.90 + 0.85 + 0.80) / 3 ≈ **0.85**.
* **Submission Type:** Special
  + **Weight:** 0.75 (33 verified submissions).
  + **Rationale:** Novel technologies requiring cadaveric tissue.
* **Processing Time:** >172 days
  + **Weight:** 0.75 (above mean processing time).
  + **Rationale:** Complex devices often involve tissue use.
* **Geographic Location:** California
  + **Weight:** 0.65 (16 verified submissions).
  + **Rationale:** High concentration of relevant companies.

**External Variables**

* **Market Position:** Market Leader
  + **Weight:** 1.0 (AI-estimated).
  + **Rationale:** Higher likelihood of needing tissue resources.
* **R&D Focus:** Strong
  + **Weight:** 1.0 (AI-estimated).
  + **Rationale:** Active development correlates with tissue use.
* **Collaboration History:** Strong
  + **Weight:** 1.0 (AI-estimated).
  + **Rationale:** Open partnerships increase tissue likelihood.
* **Financial Health:** Strong
  + **Weight:** 1.0 (AI-estimated).
  + **Rationale:** Financially stable for tissue investments.
* **Regulatory History:** Positive
  + **Weight:** 1.0 (AI-estimated).
  + **Rationale:** Strong compliance increases likelihood.

**Calculating Overall Likelihood**

**Total Variables:** 11  
**Sum of Weights:** 9.95

**Overall Likelihood:**  
9.95/11≈0.909.95 / 11 ≈ 0.909.95/11≈0.90 or **90%**.

**Example 2: Low Likelihood Applicant**

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**Applicant Details**

* **Company Name:** DigiHealth Solutions
* **Device Name:** eCare Monitoring Software

**Applicant Characteristics**

**Internal Variables**

* **Advisory Committee:** Radiology (RA)
  + **Weight:** 0.30 (low correlation).
  + **Rationale:** Minimal tissue association.
* **Product Code:** LLZ (Diagnostic Ultrasound Transducer)
  + **Weight:** 0.25 (low relevance).
  + **Rationale:** Imaging devices rarely involve tissue.
* **Device Name Keywords:** "Software," "Monitoring"
  + **Weights:**
    - "Software": 0.20
    - "Monitoring": 0.20
  + **Average Weight:** (0.20 + 0.20) / 2 = **0.20**.
* **Submission Type:** Traditional
  + **Weight:** 0.50 (standard submissions).
  + **Rationale:** Lower likelihood of tissue use.
* **Processing Time:** <162 days
  + **Weight:** 0.50 (below mean).
  + **Rationale:** Short processing time suggests simplicity.
* **Geographic Location:** Idaho
  + **Weight:** 0.50 (other regions).
  + **Rationale:** Variable relevance.

**External Variables**

* **Market Position:** Emerging Company
  + **Weight:** 0.40 (AI-estimated).
  + **Rationale:** Limited market presence.
* **R&D Focus:** Limited
  + **Weight:** 0.30 (AI-estimated).
  + **Rationale:** Focused on software, not tissue.
* **Collaboration History:** Limited
  + **Weight:** 0.30 (AI-estimated).
  + **Rationale:** Few partnerships.
* **Financial Health:** Weak
  + **Weight:** 0.30 (AI-estimated).
  + **Rationale:** Budget constraints limit tissue investment.
* **Regulatory History:** Neutral
  + **Weight:** 0.50 (AI-estimated).
  + **Rationale:** Average compliance.

**Calculating Overall Likelihood with Negative Factors**

**Initial Sum of Weights:** 4.15

**Negative Factors Applied:**

* **Software-Only Indicator:** -0.15
* **No Tissue-Related Terms:** -0.10
* **Digital Focus:** -0.08

**Adjusted Sum of Weights:**  
4.15−(0.15+0.10+0.08)=3.824.15 - (0.15 + 0.10 + 0.08) = 3.824.15−(0.15+0.10+0.08)=3.82

**Overall Likelihood:**  
3.82/11≈0.353.82 / 11 ≈ 0.353.82/11≈0.35 or **35%**.

**Conclusion**

These examples illustrate the AI chain of thought:

1. **High Likelihood Applicant**: Scores approximately **90%**, aligning with strong tissue-use indicators.
2. **Low Likelihood Applicant**: Scores approximately **35%**, effectively differentiating it as a low-priority case through adjusted weights and negative factors.

By refining weights and introducing negative factors, the system achieves better differentiation between applicants, enabling targeted engagement efforts.

Would you like to expand this with additional cases or further insights?