**FDA510k\_AI\_Granular\_Weights\_and\_Decision\_Framework\_2024-12-19**  
*(Dated: 12/24/2024)*

**1. Introduction**

This document provides a **granular breakdown** of the current weights used in our AI-driven 510(k) decision framework, along with **explanations** for how each component influences the final calculation. The content reflects our latest updates and clarifications as of **December 24, 2024**.

**2. Weighting Pillars & Definitions**

1. **Advisory Committee (AC) & Val**
   * **Orthopedic (OR)** = 0.85
   * **Neurology (NE)** = 0.75
   * **Cardiovascular (CV)** = 0.58
   * **Dental (DE)** = 0.55
   * **Surgery / Plastic (SU)** = 0.50
   * **Gastro-Uro (GU)** = 0.20
   * **Radiology (RA)** = 0.20
   * **Hematology (HE)** = 0.20
   * **Hospital (HO)** = 0.20
   * **Physical Medicine (PM)** = 0.20
   * **Anesthesiology (AN)** = 0.20

**Rationale**: AC weighting reflects historical FDA data on device complexity/risk. Orthopedics is generally higher due to implants/fixation complexity; Radiology or Gastroenterology often lower if less invasive.

1. **Product Code (PC) & Val**
   * If explicitly stated, we use the corresponding code’s historically validated weighting.
   * **Unknown or unlisted** → default 0.20.

**Rationale**: The product code weighting partially reflects the device classification but is generally **less** impactful than AC weighting.

1. **Keywords (KW) & Val**
   * **High-value** (Bone, Spinal, Implant, Fusion, Syndesmosis, Ankle, Knee, etc.) → 0.85
   * Else → 0.20

**Rationale**: KW helps detect devices involving direct orthopedic or high-tissue interfaces. This triggers synergy if combined with AC=OR or NE.

1. **Submission Type (ST) & Val**
   * **Traditional** = 0.60
   * **Special** = 0.70
   * **Abbreviated** (approx.) = 0.60

**Rationale**: Special 510(k)s have slightly higher weighting for quicker but well-defined modifications. Traditional is neutral.

1. **Processing Time (PT) & Val**
   * Typically:
     + **<162 days** = 0.50
     + **162–172 days** = 0.60
     + **>172 days** = 0.65
   * In practice, we often default to 0.50 if not stated.

**Rationale**: Longer processing times slightly raise the weighting, reflecting additional complexity.

1. **Geographic Location (GL) & Val**
   * **US** = 0.60
   * **Other** (KR, CN, JP, etc.) = 0.50

**Rationale**: Devices with US-based development or manufacturing sometimes have higher submission clarity, but difference is moderate.

**3. Additional Factors & Negative Penalties**

1. **Negative Factor (NF)**
   * **−2.0** for purely cosmetic devices (e.g., hair removal with no therapeutic claims).
   * **−0.20** for purely diagnostic software lacking any therapeutic element.
   * **none** if the device is standard or has some therapeutic component.

**Rationale**: Cosmetic devices are penalized heavily based on prior FDA data, while purely diagnostic software is penalized less but still noted.

1. **Synergy**
   * **+0.15** if **AC=OR or NE** AND **KW** in {Bone, Spinal, Implant, Fusion, Syndesmosis, etc.}

**Rationale**: Reflects a clinical synergy observed between orthopedic/neurology advisory committees and high-value keywords, historically indicating more substantial tissue impact or device complexity.

**4. Calculating the Final Score**

Each record’s numerical factors (AC + PC + KW + ST + PT + GL) are summed up. We then apply:

1. **Subtract Negative Factor** (if any).
2. **Add Synergy** (if triggered).
3. **Divide by 6** (the total number of weighted columns, excluding NF or synergy).

Final Score=(AC+PC+KW+ST+PT+GL)±NF±Synergy6\text{Final Score} = \frac{\bigl(\text{AC} + \text{PC} + \text{KW} + \text{ST} + \text{PT} + \text{GL}\bigr) \pm \text{NF} \pm \text{Synergy}}{6}Final Score=6(AC+PC+KW+ST+PT+GL)±NF±Synergy​

**5. Categorization**

We interpret the resulting numeric value as a **percentage** (multiply by 100). Current thresholds:

* **High** = >60%
* **Moderate** = 50–60%
* **Low** = ~40–49%
* **Almost None** = <10%

**6. Recent Updates & Notes**

* **Added “Syndesmosis” & “Ankle”** to the high-value KW list after Q4 2024 feedback from orthopedic specialists.
* **Fine-tuned** negative factor application for hair-growth combs or partially cosmetic devices to ensure we only apply −2 if the label is “purely cosmetic.”
* No additional synergy expansions or weighting changes were introduced as of December 2024.

**7. Conclusion**

Our **FDA510k\_AI\_Granular\_Weights\_and\_Decision\_Framework\_2024-12-19** reflects the latest refinements to synergy rules, penalty logic, and weighting columns. All changes and justifications align with our prior internal research, ensuring continued **transparency** and **consistency** in 510(k) device scoring as of **December 24, 2024**.

**Please contact the Regulatory AI Oversight Team** for further discussion on synergy triggers, negative factor thresholds, or additional weighting expansions.