**FDA510k\_AI\_New\_Insights\_from\_Recent\_Analysis\_2024-12-19**  
*(Dated: 12/24/2024)*

**1. Introduction**

This document summarizes **new insights** derived from our **recent 510(k) analyses**, focusing on how real-world device submissions are influencing our AI decision logic. All observations are current as of **December 24, 2024**.

**2. Key Observations**

1. **Expanded Keyword Overlap**
   * In the past quarter, **devices labeled as “ankle” or “humeral”** continue to show synergy with AC=OR, confirming that our updated bone-keyword approach remains valid.
   * **Spinal** vs. **Spine** references: The system is effectively recognizing them as synonyms, ensuring synergy is triggered appropriately.
2. **Borderline Cosmetic vs. Therapeutic**
   * A handful of hair-growth or skin-therapy devices remain in a **gray zone** between cosmetic and therapeutic. Our negative factor rules (−2 for purely cosmetic) may require more nuance.
   * We’ve observed an uptick in devices claiming partial cosmetic benefits but also featuring real therapeutic actions (e.g., laser scalp therapy). Currently, we do **not** penalize these devices with −2 unless the labeling is unequivocally cosmetic.
3. **Diagnostic Software Nuances**
   * Some software solutions include both diagnostic and clinical decision support features. We apply −0.20 only when the device is purely diagnostic. If there is any integrated therapeutic or interventional aspect, we refrain from penalizing.
   * This distinction has helped **avoid over-penalizing** multi-function solutions.
4. **Product Code Variability**
   * Certain newer product codes not explicitly listed in our model default to 0.20. We are reviewing ways to refine these codes once we gather enough clearance data.

**3. Potential Enhancements**

1. **Segmented Negative Factor for Cosmetic-Like Devices**
   * We may refine negative factors with **tiered** penalties (e.g., −1 for partial cosmetic claims) if future FDA clarifications distinguish partial from purely cosmetic claims more clearly.
2. **Adaptive Synergy**
   * We are considering whether synergy might be **incremental** (e.g., +0.10 or +0.15) based on how many bone- or implant-related keywords appear, rather than a single uniform +0.15.
3. **Geographic Weighted Tuning**
   * Several submissions from EU-based manufacturers suggest deeper weighting differences might be needed between certain geographies. No final decision has been made yet.

**4. Conclusion**

These **new insights** underscore how subtle real-world distinctions—particularly in borderline cosmetic devices and multi-function diagnostic software—shape the evolving 510(k) analysis approach. Ongoing internal evaluations ensure we keep the **AI model fair and accurate**, reflecting actual FDA considerations.

**For Further Discussion**  
Please contact the **Regulatory Data Analytics Team** for additional details on any planned adjustments or to share feedback regarding borderline submissions.

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