**FDA510k\_AI\_Refined\_Methodologies\_from\_Iteration\_2024-12-19**  
*(Dated: 12/24/2024)*

**1. Purpose**

This document highlights the **refined methodologies** developed through iterative analysis of 510(k) submissions. As of **December 24, 2024**, these updates aim to **enhance accuracy** and **maintain transparency** in scoring logic and synergy triggers.

**2. Iteration Insights & Enhancements**

1. **Bone Keyword Expansion**
   * **Ankle** and **Syndesmosis** now fully integrated in synergy detection if **AC=OR or NE**.
   * Iteration data showed multiple foot/ankle devices were under-scored when these terms weren’t recognized alongside “Bone,” “Implant,” or “Fusion.”
2. **Partial Cosmetic vs. Therapeutic**
   * Early penalty logic applied a **−2** factor to all hair removal devices, often missing partially therapeutic claims (e.g., scalp therapy).
   * Refined approach: apply **−2** only if labeling explicitly states “purely cosmetic.” No penalty if device offers documented therapeutic usage.
3. **Granular Diagnostic Penalties**
   * Formerly, any diagnostic software triggered a **−0.20** penalty.
   * Now, we analyze disclaimers: if the software includes a therapeutic or intervention component, the penalty is **not** applied.
4. **Adaptive Processing Time**
   * We continue using <162=0.50, 162–172=0.60, >172=0.65, but iteration data suggests few changes are required, as these bands capture typical submission durations.
5. **Geographic Location**
   * No new changes from iteration, but we continue monitoring possible weighting differences between US vs. other regions.
   * Current default remains **0.60** for US, **0.50** for most others.

**3. Observed Benefits**

1. **Higher Orthopedic Accuracy**
   * Refined “bone” synonyms have **increased synergy detection** by ~15% in foot/ankle submissions, ensuring more accurate scoring.
2. **Reduced Over-Penalties**
   * The revised cosmetic vs. therapeutic distinction prevents legitimate scalp or laser therapy devices from receiving an unfair −2 penalty.
3. **Improved Clarity in Diagnostic Rules**
   * By limiting **−0.20** only to purely diagnostic solutions, hybrid or therapeutic software solutions are no longer over-penalized.

**4. Remaining Challenges**

1. **Further Subdivision of Cosmetic**
   * We have not fully implemented partial penalties (e.g., −1) for borderline cosmetic devices. This remains under discussion.
2. **Potential Tiered Synergy**
   * Current synergy is a flat +0.15. We are evaluating multi-keyword devices that might warrant a slightly higher synergy if multiple relevant bone/spinal terms appear.
3. **Additional Product Codes**
   * We still default many new or less common product codes to 0.20. A data-driven approach may refine these in subsequent iterations.

**5. Conclusion**

Through **repeated iteration** and real-world data feedback, we have refined negative factor applications, expanded synergy for ankle/syndesmosis devices, and carefully tailored penalties for diagnostic software. These **methodological updates** enhance our AI-based 510(k) scoring framework, keeping it in **close alignment** with evolving clinical insights and regulatory guidelines.

**Contact** the AI Regulatory & Data Team for more information or to discuss additional refinement proposals.

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