**Alignment with Initial Research and Reasons for Changes**

**Initial Research Context (Original Document Excerpts):**

* Advisory Committee (AC) Weights were originally higher and more rigid:
  + Orthopedic (OR): 1.0
  + Neurology (NE): 0.9
  + Dental (DE): 0.8
  + Cardiovascular (CV): 0.7
  + Others: 0.6
* Product Codes (PC) were similarly high and narrow:
  + HRS, MQV: 1.0
  + NKB: 0.95
  + Others: 0.6 to 0.9
* Keywords were uniformly high:
  + “Allograft”/“Graft”: 1.0/0.95
  + “Bone,” “Implant,” “Spinal,” “Fixation”: around 0.9
  + Others: 0.7 to 0.85
* Submission Type, Processing Time, and Geographic Location also had higher baseline values, often starting at 0.7–0.9 for top categories.
* External Variables (Market Position, R&D, etc.) had very high weights (0.7 to 1.0), assuming strong correlations.

**Rationale for Original Framework:**  
The initial research was a first, more optimistic approximation. It reflected an assumption that all known client companies use cadaveric tissue and thus started from higher baseline weights. This baseline presumed stronger, more uniform correlations with tissue use for most committees and product codes.

**Key Changes and Their Justifications**

1. **Reduced Baseline Weights for Certain Committees and PC Codes:**
   * **From OR=1.0 to OR=0.85; NE=0.9 to NE=0.75; CV=0.7 to CV=0.58**  
     **Why:** Further analysis and literature review indicated that not all devices within these committees equally require cadaveric tissue. Orthopedic remained highest but slightly lowered to 0.85 to allow more nuanced scoring. Neurology was reduced to 0.75 because not all neuro devices (e.g., VR-based therapies) need cadaveric labs. Cardiovascular dropped from 0.7 to 0.58 since many simple CV devices are tested on animal models or simulations rather than human cadavers.

This shift acknowledges a more realistic range of devices and prevents overestimating tissue usage likelihood for simpler or non-implant devices.

1. **Introduction of “Others” at 0.20 (Previously 0.6):**
   * Originally, even “Others” started at 0.6. We lowered it to 0.20. **Why:** Detailed case studies showed that categories like Radiology, Ophthalmic, Physical Medicine (PM), Anesthesiology (AN), and pure software tools rarely justify cadaveric use. A lower baseline ensures these devices start from a more realistic low-likelihood baseline.
2. **Adjusted Product Code and Keyword Weights:**
   * Originally, PC codes like HRS, MQV were all at 1.0. Now they are slightly lower (HRS=0.80, MQV=0.78, NKB=0.75). **Why:** Even within strongly tissue-related product codes, not every device is equally likely to use cadaveric tissue. This allows more room for keywords to refine the score.
   * Keywords also became slightly more differentiated (e.g., “Bone,” “Implant” now 0.85 instead of 0.9, “Graft” still high at 0.90), adding nuance and preventing uniformly maxed-out scores. This is to better reflect gradations between synthetic grafts vs. human allograft materials.
3. **Refined Negative Factors:**
   * Originally no explicit negative factors for diagnostic or cosmetic devices were mentioned. Now we apply -0.20 for purely diagnostic/software devices and -2.00 for cosmetic devices. **Why:** This emerged from discovering many non-tissue or cosmetic devices in the dataset. Without negative adjustments, such devices would score artificially high. The negative factors align the model with realistic expectations, ensuring certain device categories correctly map to “Almost None” for tissue usage.
4. **Handling of Special Cases like VR Therapy Devices:**
   * Initially, VR or digital therapeutics addressing neurological conditions would have been lumped under Neurology (NE=0.9 originally), inflating their score. **Change:** We now classify them under “Others” (0.20) to reflect no cadaveric involvement. This is a significant conceptual refinement that recognizes the difference between a neurosurgical implant and a VR headset for pain management.

**Why:** This change was necessary after practical examples showed VR therapy devices scoring unrealistically high. It aligns the final model more closely with reality and the originally stated goal of scientific validity.

1. **Slight Adjustments to Submission Type, Processing Time, and Geographic Location:**
   * The initial model used slightly higher weights (e.g., Special=0.9 vs. now 0.70; >185 days=0.9 vs. now >172=0.65). **Why:** With experience, we saw that these secondary variables should influence scores less drastically. The refined weights strike a balance that allows these factors to nudge the score rather than dominate it.

**Overall Alignment with Initial Methodology**

**Core Concept:**  
The original intent was to use internal variables and external factors to produce a scientifically valid likelihood score for cadaveric tissue use. That core concept is maintained. We still use Advisory Committee, Product Codes, Keywords, Submission Type, Processing Time, Geographic Location, and external factors (if available) to calculate a score.

**What Changed:**

* We introduced a more nuanced, evidence-based scaling that better distinguishes between device types.
* Decreased some overly optimistic baseline weights to reduce uniformly high scores.
* Introduced negative factors and refined the range of keyword/product code associations.
* Adapted the approach for modern device categories (like VR therapeutics), which were not fully accounted for in the initial simplistic model.

**Why Changes Were Made:**

* **Realism and Validation:** After reviewing many cases, it became clear that not all devices in certain committees require cadaveric tissue. The initial model was more uniform and less discriminating.
* **Granularity:** The initial model had broad ranges (e.g., “Other Codes: 0.6 to 0.9”). Now we have a default “Others=0.20,” creating a clearer baseline.
* **Modern Device Types:** The original framework assumed a strong linkage for all NE or OR devices. Encountering VR, cosmetic, purely digital, or diagnostic devices revealed the need for conditional logic and negative factors.
* **Data-Driven Adjustments:** Observing how scores came out for different device examples prompted fine-tuning to avoid overestimation.

**Conclusion**

Yes, the final granular weights document still aligns with the initial research’s overarching methodology (using internal and external variables to determine likelihood) but has evolved significantly. The changes—reduced baselines, introduced negative factors, and special handling for certain device types—were made to better reflect real-world practices, complexity, and current industry patterns in cadaveric tissue use.

In other words, we started from a foundation of scientifically valid weights as initially described and adjusted them based on iterative learning, case-by-case analysis, and more realistic assumptions, all while keeping the original intent: to produce the most scientifically valid and context-aware likelihood estimates possible.