**Version-Control Summary (Project State as of 2024-12-19)**

**Project Purpose:**  
We are developing and refining a predictive model to estimate the likelihood that FDA 510(k) devices will require cadaveric tissue for research, education, and training. The model uses internal variables (Advisory Committee, Product Codes, Keywords, Submission Type, Processing Time, Geographic Location) and, potentially, external variables. Through iterative analysis, we’ve introduced nuanced weighting, negative factors, synergy rules, and considered how location and international manufacturing hubs influence the final scores.

**Core Variables & Current Weights:**

* **Advisory Committee (AC):**
  + OR (Orthopedic): 0.85
  + NE (Neurology): 0.75
  + DE (Dental): 0.55
  + CV (Cardiovascular): 0.58
  + SU (General/Plastic Surgery): 0.50
  + Others (e.g., RA, PM, AN, MI, CH, GU, OP, PA): 0.20
* **Product Codes (PC):**
  + HRS=0.80, MQV=0.78, NKB=0.75, OVD=0.70
  + Others=0.20
* **Keywords (KW):**
  + Allograft=1.0, Graft=0.90
  + Bone/Spinal/Implant/Fusion/Knee/Hip/Shoulder/Joint=0.85
  + Bone Putty=0.90
  + Fixation=0.75
  + Neutral=0.20
  + Cosmetic/Aesthetic=0.10
* **Submission Type (ST):**
  + Special=0.70, Traditional=0.60, Direct=0.50
* **Processing Time (PT):**
  + 172 days=0.65
  + 162–172 days=0.60
  + <162 days=0.50
* **Geographic Location (GL):**
  + California (CA)=0.60, NE US=0.55, Midwest=0.55, Others=0.50  
    *(Potential Future Adjustment for International Regions:* If data shows countries like China, S. Korea, Taiwan, Japan rely less on cadaveric training and more on manufacturing, consider lowering their weight to 0.45 or 0.40.)
* **Negative Factors (NF):**
  + Cosmetic/Aesthetic: -2.00
  + Diagnostic/Software-only: -0.20
  + Clearly Non-tissue (sparingly used): -0.20

**Scoring Formula:**  
Final Score = (Sum(AC+PC+KW+ST+PT+GL) - NF ± Synergy) / 6

**Categories:**

* Almost Certain: ≥90%
* Very High: 75–89%
* High: 60–74%
* Moderate: 45–59%
* Low: 25–44%
* Very Low: 10–24%
* Almost None: <10%

**Synergy Rules:**

* If (AC=OR or NE) AND (KW includes “Implant” or “Bone” or “Fusion”), add +0.15 to the sum before division.
* If (AC=OR or NE) AND (PC in {HRS,MQV,NKB}) AND (KW includes “Graft” or “Allograft”), add +0.20 to the sum before division.
* Synergy ensures high-likelihood devices (e.g., neurosurgical implants, orthopedic bone grafts) reach Very High or Almost Certain scores, better reflecting real-world usage.

**VR and Cosmetic Devices:**

* VR therapy devices (non-implant) fall under Others (0.20) and typically score low since they lack tissue-related keywords.
* Cosmetic devices receive a -2.00 NF, pushing them to Almost None, reflecting a near-zero likelihood of cadaveric tissue use.

**Location Considerations and Future Directions:**

* We recognized that some countries heavily involved in manufacturing (like China, S. Korea, Taiwan, Japan) might have less cadaveric-based R&D. Once credible data is obtained (via WHO, OECD, APACMed, etc.), we can differentiate these locations by assigning them lower GL weights than 0.50.
* This future step would create a data-driven location-based adjustment, ensuring devices from low-cadaveric training regions do not score unrealistically high.

**Key Insights Learned Today:**

1. **Synergy Implementation:**  
   Adding synergy effects helped move devices like orthopedic bone putty from High to Very High, aligning with the reality that such devices almost certainly undergo cadaveric testing.
2. **Refinement of Category Thresholds and Keywords:**  
   We confirmed that strong tissue indicators (Implant, Bone, Fusion, Graft) plus synergy push scores appropriately higher.
3. **Confidence in the Device-Level Approach:**  
   Seeing some devices from known cadaver-using companies still score low validates the device-specific logic. Not all products from a cadaveric-savvy company will require tissue usage, which the model now reflects accurately.
4. **VR and Cosmetic Scenarios Confirmed:**  
   VR therapy devices and cosmetic products consistently land in low or almost none categories, matching real-world expectations.
5. **Need for International Data:**  
   We established that to further refine location-based weighting, external data from reputable sources is needed. Future prompts to AI with real-time internet access may gather region-specific training or R&D indicators.

**Recommended Next Steps:**

* If possible, gather real-time data on international R&D practices from the suggested reputable sources.
* Adjust location weights accordingly to reflect manufacturing-heavy vs. cadaveric-R&D-heavy regions.
* Continue testing synergy rules on a variety of devices to ensure balanced scoring across all device types.