**Granular Weights and Decision Framework for Cadaveric Tissue Likelihood**

**Purpose**

This advanced reference document serves as a guide to applying predictive weights to a wide range of FDA 510(k) devices, incorporating recent insights. It breaks down advisory committees into subcategories, refines product code handling, and introduces fine-grained logic for keywords, device functions, and negative factors. Through these granular rules, we aim to maximize accuracy in estimating which devices are realistically associated with cadaveric testing for research, education, or surgical training.

**Core Principles**

1. **Start with Advisory Committee Weight:**  
   This sets a baseline likelihood based on the general domain of the device.
2. **Refine with Product Code and Keywords:**  
   Specific product codes and keywords can significantly raise or lower the likelihood. Implants, grafts, and bone-related devices increase it; diagnostic or non-tissue terms keep it low.
3. **Adjust Using Submission Type and Processing Time:**  
   These serve as subtle modifiers, not primary drivers, but can slightly tilt the score.
4. **Apply Geographic Location Weight:**  
   Location provides minor variation (up to ±0.10 in final average).
5. **Add Negative Factors Where Applicable:**  
   If the device is purely cosmetic, diagnostic software, or known to avoid tissue usage, apply negative factors.
6. **Consider Special Cases (e.g., VR devices):**  
   If a device falls outside the standard patterns (like VR therapy for pain), revisit the AC and KW assignments to ensure realism.

**Advisory Committee (AC) Weights (Granular Breakdown)**

* **Orthopedic (OR): 0.85**
  + **Rationale:** Orthopedic implants (knee, hip, spinal), bone grafts, fusion devices commonly tested in cadaver labs.
  + **Subcategories:**
    - Joint replacement or fusion implants: OR=0.85 stands.
    - Orthopedic accessories (e.g., simple tools not involving bone directly): Consider treating as OR but apply neutral keywords.
* **Neurology (NE): 0.75**
  + **Rationale:** Cranial implants, spinal stimulators, neural navigation systems often tested on cadavers.
  + **Subcategories:**
    - Complex neural implants (deep brain stimulators, cranial fixation): Keep NE=0.75.
    - Non-invasive digital therapeutics (e.g., VR-based pain management without implants): Do **not** default to NE. Classify as Others=0.20 to avoid inflated scores.
* **Cardiovascular (CV): 0.58 (Reduced)**
  + **Rationale:** Less direct cadaver use for simple catheters and guidewires, more often animal models or simulators.
  + **Subcategories:**
    - Complex structural heart implants (e.g., valves) might still justify CV=0.58.
    - Simple guidewires, diagnostic catheters: still CV=0.58, but combined with neutral KW keeps score low.
* **Dental (DE): 0.55**
  + **Rationale:** Dental implants and bone grafts use cadaveric or anatomical models.
  + **Subcategories:**
    - Dental implants, abutments, bone graft materials: DE=0.55 appropriate.
    - Simple restorative ceramics without graft or implant keywords: still DE=0.55 but low-impact keywords.
* **General/Plastic Surgery (SU): 0.50**
  + **Rationale:** Some surgical tools may be tested in cadaver labs, but less frequently than OR or NE.
  + **Subcategories:**
    - Surgical staplers, vessel sealers: keep SU=0.50 but expect neutral/low keyword scores.
    - Cosmetic plastic surgery devices (e.g., lasers for hair removal): still SU=0.50 baseline, but cosmetic NF applied.
* **Others (e.g., RA, PM, AN, MI, CH, GU, OP, PA, etc.): 0.20**
  + **Rationale:** Imaging devices, software diagnostics, PM rehab devices, VR therapy: rarely cadaveric.
  + **Subcategories:**
    - Imaging/diagnostic software: Others=0.20, likely add diagnostic NF.
    - VR therapy devices: Others=0.20 (not NE), no NF unless cosmetic or diagnostic.
    - Rehab equipment (wheelchairs, massagers): Others=0.20, neutral KW.

**Product Code (PC) Weights (Granular)**

* **HRS: 0.80** (Bone fixation devices)
* **MQV: 0.78** (Bone void fillers/spinal grafts)
* **NKB: 0.75** (Spinal systems)
* **OVD: 0.70** (Likely implants)
* **Others: 0.20** (General, no strong tissue link)

**Granular Logic:**  
If PC is unknown but device name suggests bone/graft usage, treat PC as neutral (0.20) but rely on keywords.

**Keyword (KW) Weights (Granular)**

* **Allograft: 1.0** (Direct human tissue use, maximum relevance)
* **Graft: 0.90** (Strong indication of tissue-related usage)
* **Bone/Spinal/Implant/Fusion/Knee/Hip/Shoulder/Joint: 0.85** (Commonly cadaver-tested implants)
* **Bone Putty: 0.90** (Like graft materials)
* **Fixation: 0.75** (Implies orthopedic testing on cadavers)
* **Neutral Terms: 0.20**
* **Cosmetic/Aesthetic Terms (hair removal, skin tightening): 0.10**
* **Diagnostic-only Terms (if considered keywords):** Still 0.20, but remember diagnostic NF if purely diagnostic.

If multiple KW apply, consider the strongest or average if needed. Usually pick the highest relevant KW.

**Submission Type (ST)**

* **Special: 0.70**
* **Traditional: 0.60**
* **Direct/Other: 0.50**

ST is a minor influencer. Special submissions can indicate novel devices that might be more complex (slightly higher likelihood).

**Processing Time (PT)**

* **>172 days: 0.65**  
  Suggests complexity, possibly more invasive or requiring more scrutiny.
* **162–172 days: 0.60**
* **<162 days: 0.50**  
  Simpler or standard devices, less likely to need cadaveric validation.

If exact processing time unknown, default <162=0.50.

**Geographic Location (GL)**

* **California (CA): 0.60**
* **Northeast US (NY, NJ, CT, PA, MA, VA): 0.55**
* **Midwest US (MN, IL, OH, MI, etc.): 0.55**
* **Others: 0.50**

Small variations; no need for further granularity here.

**Negative Factors (NF) (Granular)**

* **Cosmetic/Aesthetic: -2.00**  
  Completely rules out tissue use. E.g., hair removal, cosmetic lasers.
* **Diagnostic/Software-Only Tools: -0.20**  
  Purely diagnostic assays, imaging software, VR-based diagnostic solutions. No anatomical intervention.
* **Clearly Non-tissue (If absolutely certain): -0.20**  
  E.g., simple external monitors, generic rehab devices known never to involve anatomical cadaver testing.

Consider using NF only if device is definitively known not to require anatomical studies (e.g., an assay for infectious diseases, a VR relaxation app, a cosmetic hair remover).

**Special Considerations and Archetypes**

1. **VR Therapeutic Devices (e.g., Pain Management):**
   * Assign AC=Others=0.20, as VR solutions don’t involve implant or anatomical modifications.
   * KW=Neutral=0.20 (no tissue keywords).
   * No negative factor unless diagnostic or cosmetic.
   * Result: Low final score (~30–40%).
2. **Orthopedic Implants with Bone Grafts:**
   * AC=OR=0.85, PC=MQV (0.78) or others related, KW=Bone or Graft=0.85–0.90.
   * Typically results in High (60–74%) or Very High if multiple strong keywords.
3. **Cardiovascular Catheters & Guidewires:**
   * AC=CV=0.58, no KW.
   * Typically low to moderate (~35–45%), reflecting less cadaver involvement.
4. **Cosmetic Devices (Hair Removal, Cosmetic Lasers):**
   * Baseline AC (SU=0.50 or Others=0.20), plus Cosmetic KW=0.10.
   * Apply -2.00 NF, final ~0–10%.
   * Almost None category.
5. **Diagnostic Molecular Assays, Imaging Software:**
   * AC=Others=0.20, no tissue KW.
   * Apply -0.20 NF for diagnostic.
   * Ends up ~30–35% or lower. Low or Very Low.

**Final Formula and Categories**

**Final Score = (Sum of AC + PC + KW + ST + PT + GL - NF) / 6**

Map final percentage to categories:

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

If the device falls between categories (e.g., 59.2%), trust the nearest bracket. Consider re-checking if a borderline classification makes sense.

**Conclusion**

This highly granular weighting system integrates all insights gained from extensive predictive analysis of 109 examples. By carefully selecting AC categories, adjusting PC and KW weights, applying negative factors for diagnostic or cosmetic devices, and using “Others” for digital therapeutics like VR devices, this framework achieves a realistic, literature-informed likelihood score for cadaveric tissue usage.

Use this document as a reference for future device analyses, ensuring consistent, transparent, and justifiable scoring aligned with industry best practices and the evolving understanding of device testing and validation environments.