

Predicate Device Comparison Checklist: 510(k) Readiness Tool

Step 1: Identify Suitable Predicate(s)

- Predicate cleared under same product code
- Intended use matches (e.g. diagnostic, therapeutic)
- Similar patient population and anatomical site
- Found in FDA 510(k) database (510(k) summary available)

Step 2: Compare Technological Characteristics

- Materials and design features similar
- Performance testing requirements aligned
- Software architecture/functionality documented
- Differences addressed via testing or rationale

Step 3: Labeling and Indications Review

- Labeling claims aligned with predicate
- Warnings, contraindications, and IFU reviewed
- Marketing claims do not overreach beyond predicate

Step 4: Documentation Preparation

- Predicate comparison table created (SE justification)
- Supporting test reports or data summaries included
- Primary predicate identified clearly
- Multiple predicate strategy justified (if applicable)

