Medical Device Classification Checklist – FDA Step-by-Step Guide

Step 1: Define Your Product's Purpose

- Intended use is clearly documented
- Indications for use support clinical or wellness positioning
- Claims related to performance and safety reviewed for diagnostic, or therapeutic, impact

Step 2: Review the Device Definition (21 CFR 801.3)

- Product meets at least one criterion under FDA's medical device definition
- Product does not rely solely on chemical action (else could be a drug)
- Product is not metabolized by the body

Step 3: Checking and Identifying Regulatory Requirements

- Any of the FDA Regulations in sub-chapter J of 21 CFR should be applicable.
- Considered examples from FDA general wellness guidance
- Confirmed product code and device class

Step 4: When in Doubt

- Consider filing a 513(g) request
- Consider submitting a Q-sub/pre-sub for feedback
- Document classification rationale in internal strategy documents