

## 510(k) Decision-Making Checklist

### Device identification and description

- Device name, model, and high-level description of its intended function and major components.

### Regulatory classification review

- Determine device classification, regulation number, and product code under the FDA classification regulations.

### 510(k) exemption assessment

- Confirm whether the device type is exempt from the 510(k) requirement.

### Predicate device identification

- Identify a legally marketed predicate device cleared or approved by the FDA.

### Intended use comparison

- Confirm whether the new device has the same intended use as the predicate device.

### Technological characteristics comparison

- Evaluate whether the device has the same technological characteristics as the predicate such as design, materials, energy source, and operating principles.

### Assessment of technological differences

- If differences exist, determine whether they raise new or different questions of safety or effectiveness.

### Scientific evaluation strategy

- Determine whether existing scientific methods and testing can address any technological differences.

### Performance data requirements

- Identify the types of evidence needed (e.g., bench testing, software validation, biocompatibility, electrical safety).

### Substantial equivalence determination

- Assess whether available information can demonstrate the device is as safe and effective as the predicate device and therefore meets the substantial equivalence criteria under the Federal Food, Drug, and Cosmetic Act (FD&C Act).