



Use this FORM to document whether or not the proposed design changes require a 510(k) submission. Attach a copy of the completed ECR/ECO cover sheets to this completed FORM. Add the completed FORM to the device's Design History File.

**1.0 BASIC INFORMATION**

DEVICE NAME:

ECR/ECO #:

ECR/ECO ASSIGNED TO: \_\_\_\_\_ Print Name \_\_\_\_\_

ECR/ECO cover sheets attached?

YES  NO

**DESIGN CHANGE DESCRIPTION:**

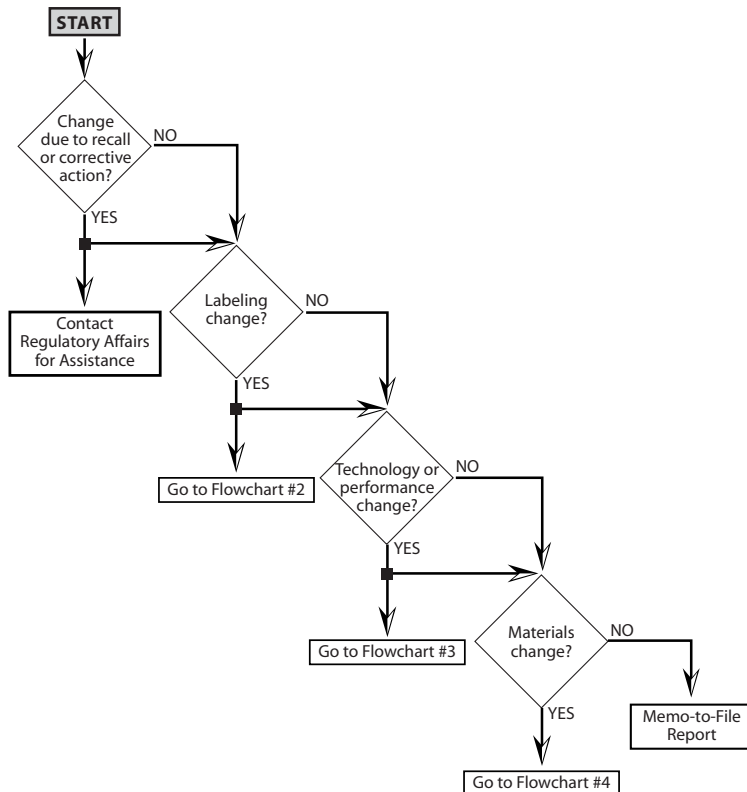
**NOTE:** "SEE ECR" is NOT acceptable.

**REASON(s) FOR THE DESIGN CHANGE:**

**NOTE:** "SEE ECR" is NOT acceptable.

**2.0 DESIGN CHANGE TYPES FLOWCHART**

Mark-up the flowchart below; attach documentation as appropriate, supporting and justifying the decision-making process.



**510(k) DECISION:**

510(k)  Memo-to-File

**3.0 APPROVALS (as applicable)**

ENGINEERING

\_\_\_\_\_  
Print Name Date

MANUFACTURING

\_\_\_\_\_  
Print Name Date

SERVICE

\_\_\_\_\_  
Print Name Date

MARKETING

\_\_\_\_\_  
Print Name Date

APPLICATIONS/TRAINING

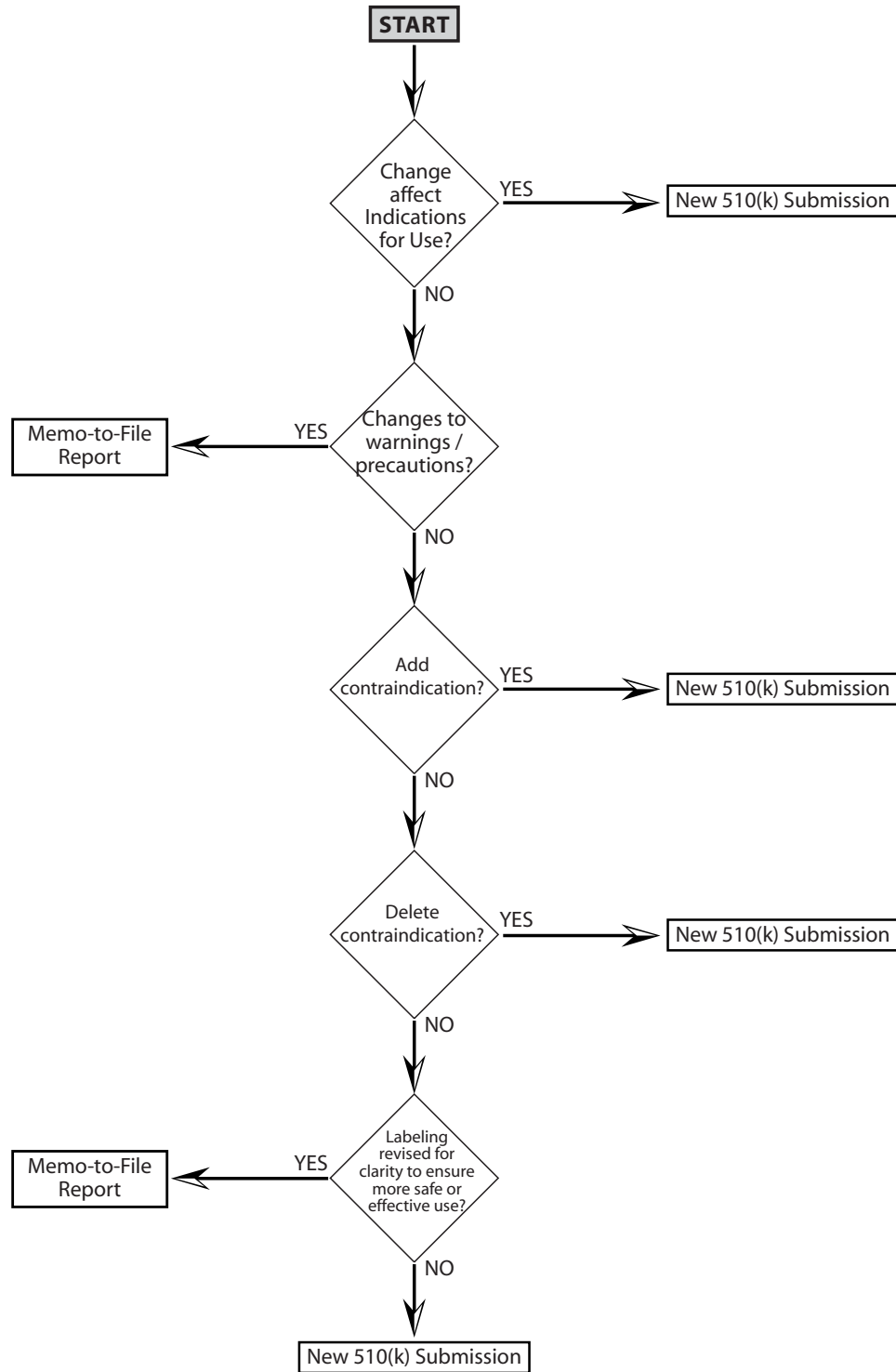
\_\_\_\_\_  
Print Name Date

QUALITY ASSURANCE

\_\_\_\_\_  
Print Name Date

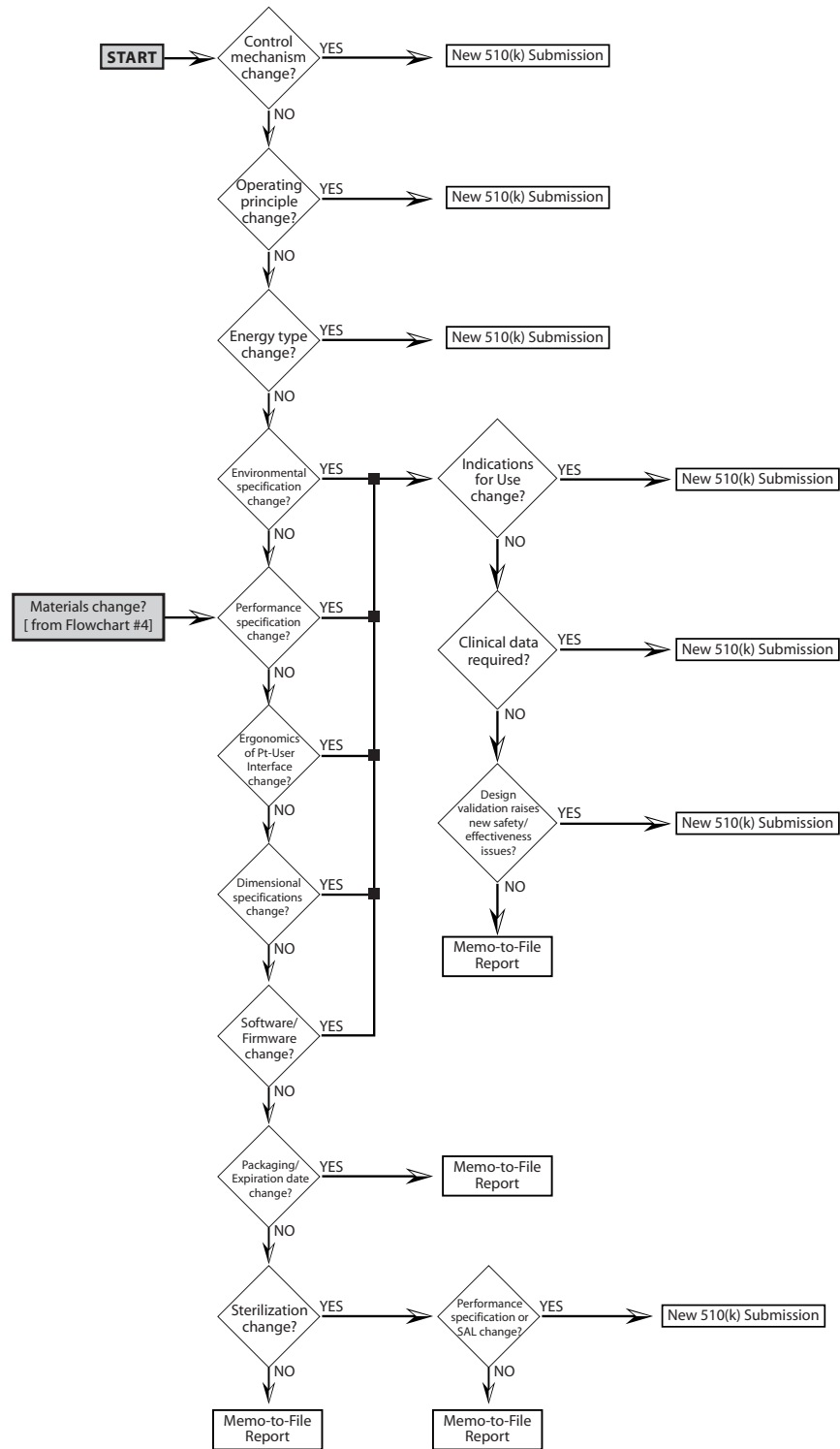
### 3.1 Flowchart #2: Labeling Changes

Mark-up the flowchart below; attach documentation as appropriate, supporting and justifying the decision-making process.



### 3.2 Flowchart #3: Technology or Performance Changes

Mark-up the flowchart below; attach documentation as appropriate, supporting and justifying the decision-making process.



### 3.3 Flowchart #4: Materials Change

Mark-up the flowchart below; attach documentation as appropriate, supporting and justifying the decision-making process.

