

Coastal Consulting Group, Ltd. www.coastalcg.com

510(k) DECISION TREE

FORM 5.6.1

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 cove	r sheets attached?		
ECR/ECO ASSIGNED TO: Print Name	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, supportin				
START	510(k) DECISIO			
_ _	510(k)	Memo-to-File		
Change	3.0 APPROV	/ALS (as applicable)		
due to recall or corrective action?	ENGINEERING			
YES	Print Name	Date		
	MANUFACTURING			
Contact Regulatory Affairs Labeling change? NO	Print Name	Date		
for Assistance	SERVICE			
	Print Name	Date		
Technology or NO		ARKETING		
Go to Flowchart #2 performance	M	AKKLIING		
Go to Flowchart #2 performance change? YES	M/ Print Name	Date		
change?	Print Name			
change?	Print Name	Date		
YES Materials NO	Print Name APPLICAT Print Name	Date TONS/TRAINING.		

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Flowchart #2: Labeling Changes 3.1 Mark-up the flowchart below; attach documentation as appropriate, supporting and justifying the decision-making process. START Change YES affect New 510(k) Submission Indications for Use? ΝO Changes to YES Memo-to-File warnings / precautions? Report ΝO Add YES contraindication? New 510(k) Submission NO Delete YES New 510(k) Submission contraindication? ΝO

Labeling revised for

clarity to ensure more safe or effective use?

New 510(k) Submission

ΝO

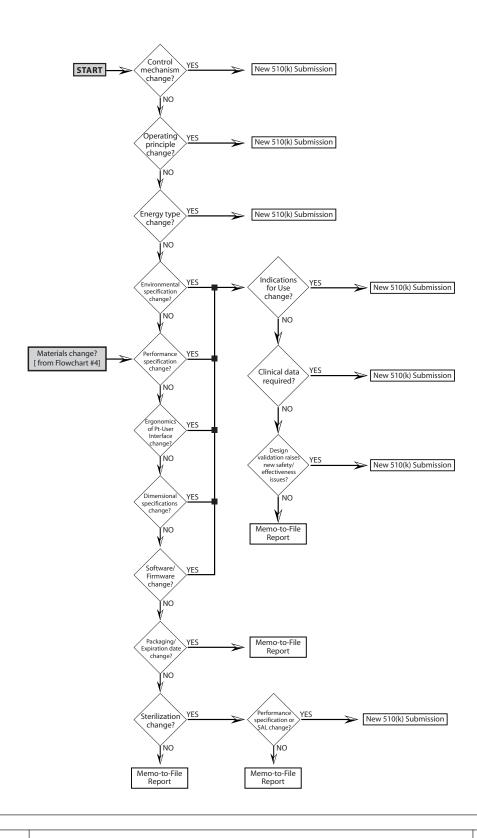
YES

Memo-to-File

Report

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.

