

MEDICAL DEVICE: Top regulatio	ns ci	ted	in V	Varn	ing L	etter	s , 20	15	
21 CFR 820.100(A): LACK OF OR INADEQUATE PROCEDURES									40
21 CFR 820.198(A): LACK OF OR INADEQUATE COMPLAINT PROCEDURES								35	
21 CFR 820.50: EVALUATION OF SUPPLIERS, CONTRACTORS, ETC., REQUIREMENTS						28			
21 CFR 820.75(A): PROCESS VALIDATIONS HAVE NOT BEEN ADEQUATELY DOCUMENTED					22				
21 CFR 820.30(G): DESIGN VALIDATION - RISK ANALYSIS NOT PERFORMED/INADEQUATE					22				
21 CFR 820.22: QUALITY AUDITS - LACK OF OR INADEQUATE PROCEDURES					20				
21 CFR 820.90(A): NONCONFORMING PRODUCT, LACK OF OR INADEQUATE PROCEDURES				17					
21 CFR 820.184: THE DEVICE HISTORY RECORD DOES NOT DEMONSTRATE THAT THE DEVICE WAS MANUFACTURED IN ACCORDANCE WITH THE DHR				15					
21 CFR 820.80(B): LACK OF/ INADEQUATE RECEIVING ACCEPTANCE PROCEDURES			12						
21 CFR 820.30(I): LACK OF/ INADEQUATE DESIGN HISTORY FILE			12						
21 CFR 820.72(A): CALIBRATION, INSPECTION, ETC. PROCEDURES LACK OF OR INADEQUATE		1	0						
21 CFR 820.181: DMR - NOT OR INADEQUATELY MAINTAINED		1	0						
21 CFR 820.70(A): PROCESS CONTROL PROCEDURES, LACK OF/ INADEQUATE PROCEDURES		9							
21 CFR 820.100(B): CORRECTIVE AND PREVENTIVE ACTION ACTIVITIES AND/OR RESULTS HAVE NOT BEEN ADEQUATELY DOCUMENTED.		9							
	0	5	10	15	20	25	30	35	40

All information found at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/default.htm?Page=1