



TABLE OF CONTENTS

Introduction to a Quality System

DESCRIPTION	PAGE #
Message from Mary Borg	2
Disclaimer	3
Taking the First Step!	4
Taking the Next Step: Introduction to Quality	5
Management Kick-off Meeting and Employee Roll-out	7
Explanation of Quality System Regulation	11
Section 820.1 Scope	11
Section 820.3 Definitions	13
Section 820.5 Quality system	14
Section 820.20 Management responsibility	15
Section 820.22 Quality audit	16
Section 820.25 Personnel	16
Section 820.30 Design controls	17
Section 820.40 Document controls	19
Section 820.50 Purchasing controls	20
Section 820.60 Identification	21
Section 820.65 Traceability	21
Section 820.70 Production and process controls	21
Section 820.72 Inspection, measuring, and test equipment	23
Section 820.75 Process validation	24
Section 820.80 Receiving, in-process, and finished device acceptance	24
Section 820.86 Acceptance	25
Section 820.90 Nonconforming Product	26
Section 820.100 Corrective and preventive action	26
Section 820.120 Device labeling	27
Section 820.130 Device packaging	27
Section 820.140 Handling	28
Section 820.150 Storage	28
Section 820.160 Distribution	28
Section 820.170 Installation	28
Section 820.180 General requirements	29
Section 820.181 Device master record	30
Section 820.184 Device history record	30
Section 820.186 Quality system record	30
Section 820.198 Complaint files	31
Section 820.200 Servicing	32
Section 820.250 Statistical techniques	33