Title

Role	Position/ DepartmentDepartment	Name	Date
Author			DD YYYY
Reviewer			DD YYYY
Approver			DD YYYY

[Company Name], Inc.

Confidential

Revision History

Ver.	Effective Date Revision Details (Reason, Changes, Affected Documents) Author/Reviewer/Approver			
Version 1.0	**Effective Date**	20XXMM00DD00YYYY		
	Reason	Initial Release(For subsequent versions, describe the reason for revision here)		
	Content	Initial Release(For subsequent versions, describe the revision content here)		
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	役　　割	**Author**	**Reviewer**	**Approver**
	Department	XXX	XXX	XXX
	Position	XXX	XXX	XXX
	Name	XXX	XXX	XXX

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Term	Definition

1. Purpose

The purpose of this policy is to establish [Company Name], Inc. (hereinafter referred to as "the Company") procedures for conducting product recalls and market corrections when medical device products exhibit nonconformities, adverse events, or potential safety concerns that require removal or correction in the marketplace.

2. Scope

This policy applies to all recall and market correction activities for medical device products manufactured, distributed, or marketed by the Company, including:

• Product recalls (removal from market)

• Market corrections (in-place modifications)

• Stock recoveries

• Product replacements requiring regulatory reporting

3. Normative References

21 CFR Part 820 Quality Management System Regulation (QMSR)

21 CFR Part 7 Enforcement Policy

21 CFR Part 806 Medical Device Reporting (MDR)

ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

FDA Guidance: Product Recalls, Including Removals and Corrections

4. Definitions

Term	Definition
Recall	A firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery. (21 CFR 7.3(g))
Market Correction	The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location. (21 CFR 7.3(k))
Market Withdrawal	A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to FDA legal action or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. (21 CFR 7.3(j))
Stock Recovery	The removal or correction of a product that has not been marketed or that has not left the direct control of the manufacturer, importer, or distributor. (21 CFR 7.3(h))
Recall Classification	The numerical designation (I, II, or III) assigned by FDA to a particular product recall that indicates the relative degree of health hazard. (21 CFR 7.3(m))
Class I Recall	A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. (21 CFR 7.3(m)(1))
Class II Recall	A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (21 CFR 7.3(m)(2))
Class III Recall	A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. (21 CFR 7.3(m)(3))
Health Hazard Evaluation	An assessment of the health hazard presented by a product being recalled or considered for recall. (21 CFR 7.3(l))
Consignee	Any person or firm who has received, purchased, or used the recalled product. (21 CFR 7.3(b))
Direct Account	Those individuals or organizations that received the product directly from the recalling firm.
Medical Device File (MDF)	The compilation of records as specified in 21 CFR 820.181 containing the general safety and performance requirements that are applicable to the device and the methods used to demonstrate that the design and manufacturing processes consistently result in medical devices that conform to their specifications. (21 CFR 820.3(s))