

1. Project Overview

Project Name

Project Lead

Department/Team

Project Start Date

Background

Objectives

2. Stakeholders & Key Contacts

Internal Stakeholders

External Stakeholders

3. Device Description

Device Name

Intended Use/Indications

Overview of Principle of Operation

Proposed Target Users

Key Features

4. Regulatory Pathway

Target Market(s)

Expected Device Classification

Relevant Regulatory Standards

Certification Requirements

5. Project Milestones

Key Milestones & Timeline

6. Resources & Budget

Key Resources Needed

Estimated Budget

7. Risks & Challenges

Key Risks

Risk Mitigation Strategies