Medical Device Development Phases and Functional Activities

	Tasks / Functional Groups	PHASE 0 Evaluation / Opportunity & Risk Analysis	Gate 0 — Product Definition Acceptance / Concept Charter	PHASE 1 Demonstration / Concept & Feasibility	Gate 1 — Feasibility Demonstrated / Initial Design Acceptance	PHASE 2 Design & Development / Verification & Validation	Gate 2 — Final Design Acceptance	PHASE 3 Final Validation / Product Launch Preparation	Gate 3 — Product Launch Acceptance / Launch Readiness	PHASE 4 Product Launch & Post-Launch Assessment
1	Cross-Functional Management	Financial Review Business Model Development		Project Core Team Selection Hire Specialists for Expertise Gaps		Cross-Functional Project Management Budgeting / Fundraising Activities		Cross-Functional Project Management Business Develop-ment Budgeting or Fundraising Activities		Cross-Functional Project Management
2	Markets & Marketing	Market Analysis Competitive Assessment "PRD" (1)		General Project Plan & Timeline Fundraising Activities Customer Input / VOC Customer Prototype Evaluation		Customer Prototype Evaluation		Product Branding Market Launch Plan / Forecast		Physical Training & Continuous Sales Efforts
3	Writing and Publications	Business Plan & Presentations Literature Search		Business Plan & Literature Search Updates		Meta Analysis White Paper Data Summary, Analysis White Paper, Publish Peer Review Papers		Meta Analysis White Paper Data Summary, Analysis White Paper, Publish Peer Review Papers		Meta Analysis White Paper, Publish Peer Review Papers
4	Research & Development	Early Risk Assessment & Concept Approach		Early Concept Prototype Design & Build Prototype Evaluation Update Design Per Review & Analysis / Multiple Discipline Input Driven Initiate & Maintain Design History File (DHF) Initial Design Risk Analysis (dFMEA)		Product Development & Test Design Verification & Validation Update Design per Review & Analysis / Multiple Discipline Input Driven Maintain DHF & Project Timeline Design Risk Analysis (dFMEA)		DHF Completion dFMEA Update & Review Final Design & Documentation Release		Sustaining Engineering / Product Improvements as Needed
5	Design Documentation	Quick CAD Layouts, Prelim. Engineering Specs		CAD Models, Minimum Drawing Set, Engineering Specification		Complete CAD Models & Drawing Set, Updated Engineering Spec, Other Design Files		Full Released Documentation Per ISO13485		DCO Maintenance
6	Industrial Design	Sketches, Renderings (Paper, Digital)		Renderings, Size / Feature Mockups, Appearance Models (Hard Foam, RP (2) Methods)		"Looks-like / Works-like" Prototypes, Aesthetic Refinement, DFMA(3) (RP & Production Methods)		"Looks-Like / Works-Like / Made-like" Cosmetic Refinement, Pre-Production Units, Packaging, (Production Methods)		Support Release
7	Legal / IP	Legal / IP Analysis, Clearance Opinion		IP Landscape Review & Review of Filings		Patent Review / Inlicense & Outlicense Review		Final Patent Review with R&D		Patent Litigation
8	Regulatory	Regulatory Path		Initial Regulatory Strategy		Regulatory Strategy Update		Regulatory Submission Obtain Regulatory Clearances (FDA, CE, UL, etc.)		Post-Market Surveillance / MDR
9	Reimbursement	Reimbursement Path		Initial Reimbursement Strategy		Finalize / Pursue Reim-bursement Strategy		Pursue Reimbursement		Update Reimbursement as Needed
10	Manufacturing & Operations	Manufacturing plan		Initiate DFM (Tooling, Fixturing)		Detailed Produc-tivity Analysis Supplier Collaboration Manufacturing & Process Engineering Initial Process FMEA (pFMEA) Order Tooling		Manufacturing / Operations Scale Up		Process Improvements as Needed
	Quality	Quality Plan		Initiate Quality Management System (QMS) / Document Control		Begin Process IQ / OQ / PQ / PPQ		Full Process Qualification Finalize Process IQ / OQ / PQ / PPQ		Update Design Control Doc as Needed Quality Audits
12	Pre-Clinical	Pre-Clinical Path		Pre-Clinical Tests		Biocompatibility Testing (If Possible)		Physician Pre-Clinical Training, Biocompatibility Testing		Physician Pre-Clinical Training
13	Clinical	Clinical Path		Assemble SAB & MAB Determine Endpoints & Variables		Clinical Validation Plan		Clinical Validation		Continued Clinical Validation
14	Data and Statistics	Market Forecast		Survey Analysis Pre-clinical Data Analysis		Survey Analysis Literature & Data Meta Analysis		Clinical Data Analysis		Summary White Paper
15	Sales	Sales Path		Sales Plan		Recruit Sales Team		Sales Training		Reps Attend Cases
	Gate 0 Decisions			Gate 1 Decisions		Gate 2 Decisions		Gate 3 Decisions		
16	Market Opportunity	Tech, Regulatory, IP Approach Feasible		Value Proposition Viable & Sustainable Product Risks Acceptable		Commercialization Readiness Design Freeze Design Output Meets Targets		Final Validations		
17	Basis for Competition	Manageable Risk & Executional Gaps		Technical Feasibility Proven & Optimized Manufacturing & Value Chain Confidence		Risk Mitigation Confirmed		Regulatory Submission, Testing Complete Sales Launch, Business Launch Plan Adjust		

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1) PRD = Product Requirements Document 2) Rapid Prototyping 3) Design For Manufacturability & Assembleability