



Roadmap Apollonia



**APOLLONIA –
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THE SOLUTION FOR A COMPLETE WORKFLOW



Overall strategy (executive view)

Target image:

- Medical device class IIb (EU) according to MDR (EU) 2017/745
- AI-based planning software (SaMD + AI Act relevant)
- Multi-Region Launch: EU → USA → Asia
- Scalable Cloud + Edge (distilled AI for medical devices)

Critical success factors:

- Early development of an ISO 13485 QMS
- AI transparency (explainability , auditability)
- Clinical evidence (not optional for IIb !)
- Clear separation: **Prototype ≠ Regulatory validated product**

PHASE 0 – Strategic preparation (Q1–Q2)

Q1 – Foundations

Business + Regulatory Setup

- Target classification: Confirm class IIb
- Regulatory Strategy (EU + FDA + Asia)
- The intended use / purpose (crucial!)
- Competitor analysis (e.g. Align , exocad)

Technically

- System architecture (Cloud + Edge + CAD/CAM integration)
- Data strategy (training data, annotation, data protection)

Quality system

- QMS structure according to:
 - ISO 13485
 - ISO 14971

Q2 – Architecture & Risk

Regulatory

- Start Risk Management File
- Software classification according to IEC 62304
- Usability Engineering Plan (IEC 62366)

Technically

- MVP Architecture
- AI pipeline (training / validation / monitoring)
- Building initial data sets

Output

- Design Input Documentation
- Regulatory Roadmap (EU + USA)

PHASE 1 – MVP & Pre-Clinical (Q3–Q6)

Q3 – MVP Development

- 3D scan processing
- Basic AI (tooth recognition, segmentation)
- First CAD automation

AI Governance

- Explainability approaches (e.g., feature attribution)
- Logging of all AI decisions

Q4 – Alpha System

- Visualization (Smile Design, Simulation)
- Initial treatment suggestions
- Human-in- the -loop mandatory

Regulatory

- Software lifecycle documentation
- Cybersecurity (important point!)

Q5 – Beta + internal validation

- Comparison: AI vs. Dental Technician
- Performance Benchmarks
- Start of AI distillation (for edge devices)

Standards

- IEC 62304 processes audit- ready
- Data protection (GDPR + international variants)

Q6 – Pre -clinical Studies

- Simulations + retrospective data
- Validation of:
 - accuracy
 - reproducibility
 - Security

PHASE 2 – Clinical Validation & Certification (Q7–Q10)

Q7 – Clinical Trial Start

- according to MDR (EU) 2017/745
- Study protocol
- Ethics Committee

Q8 – Study program

- Multicenter studies
- Real patient data
- Comparison against standard of care

Q9 – Preparing for certification

- Technical documentation complete:
 - Clinical Evaluation Report
 - Risk Management
 - Software Validation
 - Audit by Notified Body

Q10 – CE marking

- CE for Class IIb
- EU Launch (Soft Launch)

PHASE 3 – International expansion (Q11–Q14)

USA (in parallel from Q8–Q12)

- FDA Submission:
 - probably De Novo or 510(k)
- SaMD follow the guidance
- AI Change Management Plan (very important!)

Asia

- PMDA (Japan)
- NMPA
- Local clinical data are often needed.

PHASE 4 – Scaling & AI optimization (Q12–Q16)

AI distillation & edge deployment

- Large models → Small models
- Deployment on:
 - Local workstations
 - High-end tablets

Techniques

- Knowledge Distillation
- Quantization
- Model Pruning

AI Transparency (crucial for regulation!)

- Decision protocols
- Visual justifications
- Audit trail

Relation to the EU AI Act:

- High-risk AI → Full traceability required

PHASE 5 – Platform & Monetization

Implement the 3-pillar model

1. Software licenses (SaaS)
2. Production network (labs)
3. Full -service production

Scaling

- Global cloud infrastructure
- GPU cluster
- Latency optimization

CRITICAL RISKS (Relevant to investors)

1. Regulatory Risk

- IIb + AI = very high hurdles
- Delays: 12–24 months possible

2. Clinical evidence

- Without solid data → No approval

3. Data availability

- AI stands or falls on training data

4. Liability

- Poor planning → Medical harm

TIME AXIS (compact)

phase	Length of time	Goal
Phase 0	6 months	Strategy + QMS
Phase 1	12 months	MVP + Beta
Phase 2	12–18 months	Clinic + CE
Phase 3	12 months	USA + Asia
Phase 4	ongoing	AI scaling

Realistically: 3–4 years until a globally scalable product

Strategic note (very important)

We will approach Apollonia from the beginning as:

“AI- augmented medical” The decision support system is **NOT** positioned as a fully automated decision-making authority.

This reduces:

- Regulatory hurdles
- Liability risks
- Clinical requirements