



Apollonia Regulatory Market Access Overview



**APOLLONIA –
JOACHIM LUGOJAN**
THE SOLUTION FOR A COMPLETE WORKFLOW



Apollonia – Regulatory Market Access Overview

Overview: Admission pathways, overlaps, costs and timeline — Status: September 2026

Initial situation

Apollonia is an AI-powered SaMD (Software as a Medical Device) for autonomous dental treatment planning. It is seeking MDR Class IIb approval in the EU (Notified Body required). This document consolidates three research findings: (1) which authorities/regulations apply in each country and where approvals overlap, (2) the estimated costs per country, and (3) the estimated time to market access—providing a comprehensive basis for the business plan and organizational planning.

Important clarification upfront: There is no automatic global approval. The statement "If it's approved in the US, it's also approved elsewhere" does not apply anywhere. What does exist are tiered reliance / abridged pathways : countries that accept FDA or CE/MDR approval as supporting evidence, thereby reducing review time and effort – but almost always with local registration, a local representative, and local language/labeling on top of that. All cost and time estimates are planning figures from industry reports/regulatory fee schedules 2026, not binding offers.

Countries and regions, sorted by market size (national, approx. 2026, descending)

1. USA

- **Market size:** approx. USD 200–235 billion (2026)
- **Competent authority:** FDA (CDRH)
- **Core regulations / standards:** FDA SaMD framework, 21 CFR 820 → new QMSR (from February 2, 2026, aligned with ISO 13485), IEC 62304, ISO 14971; Cybersecurity §524B
- **Does it accept foreign certification as a substitute?** No – it's an independent procedure, but it does accept technical documentation from the EU/CH as input.

Estimated costs:

- A crucial decision: Apollonia is an autonomous AI treatment planning tool without an obvious predecessor product (predicate). Therefore, the de novo path is usually the appropriate one, not the more cost-effective 510(k) path.
- FDA Fee De Novo (FY2026): USD 173,782 Standard / USD 43,446 Small Business
- FDA fee 510(k), if a designation is found: USD 26,067 Standard / USD 6,517 Small Business
- Annual business establishment registration fee: USD 11,423/year
- US Agent (mandatory): approx. \$1,000 USD/year
- Estimated total project costs for a De Novo case: approximately USD 250,000–500,000+ (estimate based on fee ratio, to be verified with an FDA consultant before inclusion in the business plan); 510(k) case for comparison: USD 50,000–150,000
- **Estimated time to market:** De novo review time at the FDA: 9–12 months; including test preparation, realistically 12–18 months to market access. (510(k) would be faster at 3–9 months, but without a designation, probably not the right path)

- **Practical roadmap for Apollonia:** Plan for your own de novo certification process; the EU Technical File can be reused as supporting documentation, but it does not replace FDA review. Start in parallel with EU certification.

2. China

- **Market size:** approx. USD 47 billion (2026)
- **Competent authority:** NMPA
- **Core rule set / standard:** Independent classification (usually Class II/III for AI diagnostics/planning), often requires a local clinical study or comparative study.
- **Does it accept foreign approval as a substitute?** No – strictest independence for all markets, no recognition of FDA/CE approvals.

Estimated costs:

- Government fee Class II (imported): RMB 210,900 (~USD 30,000); Class III: RMB 308,800 (~USD 44,000)
- Local clinical trial/comparative study: not generally quantifiable, but often by far the largest cost block – calculate separately with Chinese regulatory partners.
- Estimated total costs (excluding tuition fees): approx. USD 30,000–150,000
- **Estimated time to market access:** 12–24 months for Class II, up to 36 months for Class III – plus time for any necessary local clinical trial (this is extra, not included in this figure)
- **Practical roadmap for Apollonia:** Separate, most complex procedure; for "decision support" often Class III approval with a mandatory study in China. Sensitive: Chinese investors and Swiss medtech IP are already subject to screening. Plan for the final wave.

3. EU (27 states, as a bloc)

- **Market size:** large (total for a single country significantly > China; no individual value researched)
- **Competent authority:** Notified bodies + each national authority (BfArM, ANSM, etc.)
- **Core regulations / standards:** MDR 2017/745 (Class IIb : Notified Body certification) + additionally EU AI Act (high-risk AI in the medical field: transparency, human oversight, conformity assessment) + IEC 62304, ISO 14971, ISO 13485
- **Does it accept foreign approval as a substitute?** Basic approval – once CE/MDR certified, it is valid in all 27 EU member states without individual testing.

Estimated costs:

- Notified body fees (core costs): approximately €70,000–€220,000 for the initial certification of a Class IIb product; other sources cite figures as high as €80,000–€300,000+ for Class IIa / IIb / III, averaging approximately €250,000 over 18 months for an AI diagnostic product of comparable complexity.
- Hourly rates of notified bodies: Technical file review €200–430/h, Clinical evaluation €225–545/h, QMS audit €180–440/h; Certificate issuance €100–1,300
- Planned relief (not yet final): EU reform proposal could shorten SaMD procedures in the future (e.g., to approximately €75,000 / 9 months) – currently only a legislative proposal, not legally binding, do not plan for it with certainty.
- Ongoing costs after certification: approx. €29,000–160,000+ per year (monitoring audits, certificate maintenance, EU representative, PMS/PSUR, EUDAMED maintenance)
- Additionally, the EU AI Act (parallel to the MDR, mandatory from August 2026, transition period until August 2027 for MDR products): approx. €16,800–23,000 certification costs per product unit plus approx. €29,277/year ongoing compliance costs
- Rough total initial investment: realistically around €100,000–€300,000, plus around €20,000–€35,000/year for AI Act compliance once it takes effect.
- **Estimated time to market access:** 6–18 months from complete submission; currently closer to the upper end, as notified bodies report capacity constraints in 2026 (13–18 months for initial certification is not uncommon).

- **Practical roadmap for Apollonia:** This is the initial approval from which all other markets are "derived." Important: The EU AI Act runs in addition to the MDR – two parallel conformity assessments. Start concurrently with the US assessment, as both require 12–18 months.

4. Japan

- **Market size:** approx. USD 30–44 billion (2026, depending on the source)
- **Competent authority:** PMDA / MHLW
- **Core rule set / standard:** Proprietary SaMD rule set, dedicated SaMD testing facility, proprietary accelerated software path
- **Does it accept third-party approval as a substitute?** No – independent, but comparatively faster dedicated software track.

Estimated costs:

- Ninsho (Class II) government fee : on average ~30,000 USD, total costs 30,000–80,000 USD
- Government fee for Shonin (Class III/IV): USD 20,000–120,000, total costs USD 50,000–200,000+
- DMAH (Mandatory Representative for Foreign Manufacturers): USD 15,000–50,000/year Retainer
- **Estimated time to market access:** Ninsho path (Class II): 3–6 months; Shonin path (Class III/IV): 6–36 months – more likely at the upper end for autonomous AI decision support.
- **Practical roadmap for Apollonia:** Independent PMDA procedure; EU dossier can be used as a reference, but does not replace PMDA review. Depending on the classification, plan for the timing with China as the last wave.

5. India

- **Market size:** approx. USD 18 billion (2026)
- **Competent authority:** CDSCO
- **Core rule set / standard:** Medical Device Rules 2017 + new final MDSW Guidance 2026 (software/AI explicitly covered), classes A–D according to risk
- **Does it accept foreign certification as a substitute?** Partially – foreign certifications facilitate/accelerate the process, but especially for Class C/D licenses, they do not replace the CDSCO test.

Estimated costs:

- Government fee Class B/C: USD 2,000–3,000 per location + USD 1,000–1,500 per product
- Estimated total costs: approximately USD 10,000–30,000 – one of the most affordable markets in the overview.
- **Estimated time to market access:** 5–12 months depending on the class
- **Practical roadmap for Apollonia:** Likely Class B–C depending on risk assessment; ISO 13485 mandatory, CDSCO portal (Sugam). Good candidate for the “low -hanging fruit ” wave .

6. Switzerland

- **Market size:** medium (significantly smaller than D/F/UK, but high per capita spending)
- **Competent authority:** Swissmedic
- **Core rule set / standard:** MedDO / IvDO (reflect MDR/IVDR)
- **Does it accept foreign approval as a substitute?** De facto, yes, but with additional effort: CE-MDR has been unilaterally recognized by Switzerland since the end of the MRA (2021) – but CH-REP is mandatory + mandatory swissdamed registration from July 2026. New: On March 2, 2026, a new EU-CH-MRA was signed, which is intended to restore full mutual recognition – ratification/referendum pending, full effect no earlier than 2028.

Estimated costs:

- Swissdamed registration fee: CHF 200 for the first product, CHF 20 for each additional product, capped at CHF 10,000/year
- CH-REP: Basic fee usually CHF 1,500/year plus product-dependent additional fee; market standard CHF 2,000–6,000 in the first year, then somewhat less
- No separate content-related approval review is necessary, as CE-MDR is unilaterally recognized.
- Rough total cost (in addition to EU approval): approx. CHF 3,000–8,000 in the first year, then CHF 2,000–6,000/year – the cheapest additional market
- **Estimated time to market access:** Very short once CE marking is obtained: CH-REP setup 2–4 weeks, swissdamed registration afterwards often only days to a few weeks. Practically no separate substantive review period.
- **Practical roadmap for Apollonia:** Domestic market: CE certificate + CH-REP + swissdamed registration is currently sufficient; from approximately 2028, automatic recognition without CH-REP may be possible via the new MRA.

7. UK (non-EU)

- **Market size:** medium-large
- **Competent authority:** MHRA
- **Core regulations / standard:** UKCA marking , currently transitional recognition of CE/MDR certificates
- **Does it accept foreign approvals as a substitute?** Yes, under the " Comparable Regulator Countries" Reliance Route – FDA, Health Canada, TGA, and Singapore are also accepted as references.

Estimated costs:

- Annual fee: GBP 300 per GMDN Level 2 category per year (new from April 2026); approximately 56% of manufacturers pay only this minimum amount.
- Estimated total costs: approximately USD 5,000–15,000, as CE-MDR is widely accepted.
- **Estimated time to market access:** 3–6 months (Reliance route based on the CE certificate)
- **Practical roadmap for Apollonia:** UK Responsible Person + Reliance route based on the CE-MDR certificate – comparatively simple and fast

8. Saudi Arabia

- **Market size:** approx. USD 12 billion (largest single market in the Middle East)
- **Competent authority:** SFDA
- **Core rule set / standard:** MDMA (Medical Device Marketing Authorization) via the GHAD system, stricter since the MDMA2 transition.
- **Does it accept third-party approval as a substitute?** Only as support – FDA/CE strengthens the application, but since MDMA2 they no longer replace the full technical dossier.

Estimated costs:

- MDMA fee Class C/D: SAR 21,000–23,000 (~5,590–6,130 USD)
- Authorized Representative : SAR 2,600/year (~692 USD)
- Estimated total costs: approximately USD 15,000–30,000
- **Estimated time to market access:** SFDA review time approx. 35 working days; with dossier preparation, realistically 3–6 months total.
- **Practical roadmap for Apollonia:** Full SFDA dossier required; once granted, the SFDA approval serves as a strong reference for the other GCC states.

9. Canada

- **Market size:** medium (significantly smaller than D, no precise value researched)
- **Responsible authority:** Health Canada
- **Core regulations / standard:** Canadian Medical Devices Regulations (CMDR) + mandatory MDSAP certificate for Class II–IV
- **Does it accept third-party approval as a substitute?** No, for product approval – Health Canada does not recognize FDA/CE market approval; MDSAP only covers the QMS audit (jointly with FDA/TGA/ANVISA/MHLW), not product testing.

Estimated costs:

- Class II license fee: CAD 632 (~465 USD)
- MDSAP certificate: separate audit costs, roughly USD 5,000–25,000 if handled externally.
- Estimated total costs: approximately USD 10,000–40,000
- **Estimated time to market access:** MDL issuance itself takes 15–90 days – but before that comes the MDSAP certification (QMS audit), which alone can take 6–12 months if not already available.
- **Practical roadmap for Apollonia:** Standalone Medical Device License (MDL) required, no local representation mandatory, but bilingual (EN/FR) labeling is required. Initiate MDSAP as early as possible, as it is time-critical.

10. Australia

- **Market size:** approx. USD 5–6 billion (estimate, no precise figure researched)
- **Responsible authority:** TGA
- **Core rules/norm:** Therapeutic Goods (Medical Devices) Regulations 2002, classification closely based on the MDR
- **Does it accept foreign certification as a substitute?** Yes, a genuine Reliance Passport – the Abridged one. Pathway accepts CE/MDR certificates, FDA, Health Canada, PMDA, HSA Singapore directly as proof of conformity.

Estimated costs:

- Application fee Class IIa / IIb : AUD 1,187 (~795 USD)
- Annual fee: AUD 1,230 (~824 USD)
- Estimated total costs: approximately USD 10,000–50,000 – significantly cheaper thanks to Abridged. Pathway
- **Estimated time to market access:** approx. 6–12 months for Class IIb , thanks to Reliance on the CE certificate noticeably faster than a re-certification.
- **Practical roadmap for Apollonia:** Most efficient additional market: CE-MDR certificate + Australian sponsor sufficient for ARTG entry without independent substantive review

11. UAE

- **Market size:** approx. USD 2–3 billion (estimate)
- **Competent authority:** EDE (formerly MOHAP, transfer of responsibility since 2025/26)
- **Core regulations / standard:** EDE registration, CE/FDA as a " reliance pathway " basis
- **Does it accept foreign registration as a substitute?** Partially – CE marking significantly shortens the process, but does not replace the UAE-specific registration including Arabic marking and a local representative.

Estimated costs:

- Registration fee: AED 5,000–15,000 (~USD 1,360–4,000), depending on risk class
- Estimated total costs including local representative: approx. USD 10,000–25,000
- **Estimated time to market access:** approx. 2–6 months

- **Practical roadmap for Apollonia:** Use the CE-MDR certificate as the basis for the Reliance Pathway ; then a roadmap for other GCC states.

12. Qatar

- **Market size:** small
- **Competent authority:** MoPH
- **Core regulations / standard:** National registration, usually requiring reference approval.
- **Does it accept third-party approval as a substitute?** Yes, as a prerequisite – without existing SFDA, FDA, or CE approval, it is generally not even considered.

Estimated costs:

- No hard fee figures were researched – structurally similar to the UAE
- Rough estimate: approximately USD 10,000–20,000
- **Estimated time to market access:** No reliable single figure found – structurally similar to the UAE, roughly 2–6 months to be expected.
- **A practical roadmap for Apollonia:** First secure SFDA (Saudi Arabia) or CE as a foundation, then "bring on" Qatar. Kuwait, Bahrain, and Oman are following the same pattern.

13. New Zealand

- **Market size:** small
- **Competent authority:** Medsafe
- **Core rule set / standard:** No formal prior approval – notification system (WAND database)
- **Does it accept foreign approval as a substitute?** In practice, yes – Medsafe does not require its own content review, but rather proof of approval from a reference country (FDA, EU, Health Canada, TGA, PMDA) as a notification requirement .

Estimated costs:

- No upfront registration fee – WAND notification is essentially free of charge or very inexpensive.
- Main cost block: local sponsor/representative, estimated at approximately USD 3,000–8,000 per year.
- **Estimated time to market access:** Virtually immediate – only the 30-day WAND notification after market entry is required, no prior review.
- **Practical roadmap for Apollonia:** Practically the simplest and fastest market: CE-MDR certificate + WAND notification within 30 days of market launch is sufficient.

Other smaller GCC states (Kuwait, Bahrain, Oman) follow the same pattern as Qatar: their own national registration, but SFDA/FDA/CE as an accelerating reference – a GCC-wide uniform regulatory framework (GCCMDR) is in progress, but not yet final.

Where does there actually overlap? (Summary of the "passes")

Significant overlap

(CE/MDR or FDA is actively accepted as a substitute/ reliance certificate, resulting in a noticeable reduction in processing time):

- Australia (TGA Abridged) Pathway – the clearest “real” Reliance case
- New Zealand (Medsafe /WAND – de facto no content-based double review)
- UK (MHRA Comparable Regulator Route)

- Switzerland (unilateral CE recognition, but with additional CH-REP effort; possibly fully automatic via new MRA from approx. 2028)
- UAE, Qatar, Kuwait, Bahrain, Oman (Reliance pathways, but always + local registration/language)

Weak overlap

(external approval helps, but does not replace your own full examination):

- Saudi Arabia (only supporting since MDMA2)
- India (CDSCO – helps more in lower classes than in C/D)
- Canada (MDSAP only covers QMS, not product approval)

No overlap

(completely independent procedure, both in terms of content and timing):

- USA (FDA)
- Japan (PMDA)
- China (NMPA – including often mandatory local hospital data)

An additional, non-overlapping layer: the EU AI Act

Of particular importance for Apollonia: Because it involves AI-supported, autonomous treatment planning, the EU's AI Act (high-risk classification for medical AI, mandatory from August 2026, transition period for MDR products until August 2027) applies in parallel to the MDR. This is an additional, independent conformity assessment procedure with its own costs (approx. €16,800–23,000 for certification + approx. €29,277/year ongoing) – not a replacement for the MDR, but an add-on. Similar AI-specific supplementary regimes now also exist in Australia (TGA AI Guideline 2026), China (NMPA Guidelines on AI-supported diagnostics), and the USA (FDA PCCP/GMLP Framework for AI/ML- SaMD) – each with its own requirements, and no mutual recognition between them.

Cost Summary: Priority 1 (EU, Switzerland, USA)

- **EU (MDR Class IIb + AI Act):** approx. €100,000–€300,000 one-off payment, then €50,000–€70,000 per year on an ongoing basis.
- **Switzerland (in addition to EU approval):** approx. CHF 3,000–8,000 one-time fee, then CHF 2,000–6,000 per year.
- **USA (FDA, expected De Novo):** approx. USD 300,000–550,000 one-time fee, then approx. USD 11,400/year

For a Class II product launched simultaneously in the US + EU + another Asian market, an industry source (MedDeviceGuide 2026) suggests a total budget range of USD 100,000–400,000 as a rule of thumb, depending on the chosen third market – however, this refers to 510(k) cases and is likely to be at or above the upper end for a de novo case like Apollonia.

Time summary and organizational information

- **The EU and US launches should be time-critical:** both require 12–18 months and are therefore the most time-sensitive paths. Doing them sequentially would unnecessarily extend the overall time-to-market.
- **Switzerland, UK, Australia, GCC countries:** can be "followed up" relatively quickly after EU certification (weeks to a few months), as they are based on the CE certificate.

- **Canada:** MDSAP certification is time-critical (6–12 months) – should be initiated early, regardless of the actual MDL application.
- **China and possibly Japan (Shonin pathway):** the upward time outliers (up to 36 months) – plan for them as the last wave.
- **New Zealand:** practically immediately available (30-day notification without prior review) – suitable as a quick initial proof of international market presence

Recommended order for Apollonia

- EU (MDR Class IIb) + AI Act compliance – the foundation needed for everything else; start in parallel with the US (6–18 months each)
- USA (FDA, De Novo) – largest single market, but independent and time-critical procedure (9–12 months PMDA review time); start early and in parallel with the EU, not sequentially.
- Switzerland – home market, achievable within a few weeks with CE certification + CH-REP; cheapest and fastest additional market
- Australia, New Zealand, UK, GCC (UAE/Qatar/Kuwait/Bahrain/Oman) – “Low- hanging fruit “ thanks to Reliance-Pathways based on the CE certificate, 2–12 months, moderate costs
- Saudi Arabia – worthwhile due to market size, but plan for a separate SFDA dossier (3–6 months, USD 15,000–30,000)
- accelerated with an existing EU/US dossier ; initiate the MDSAP audit for Canada early.
- Japan, China – most complex (own testing facilities, in China often local clinical data, up to 36 months) – plan for last in terms of timing, highest cost and time uncertainty