When Dental AI Is a Medical Device (TGA)

Some dental AI does not just help with admin — it reads X-rays, detects decay or triages urgency. When software makes a clinical call, it can be a regulated medical device.

When Dental AI Is a Medical Device (TGA)

> Not all dental AI is admin. Some of it reads an X-ray, flags decay or decides how urgent a patient is — and software that makes a clinical call can be a regulated medical device.

This is general educational material for dental practice owners, not legal or regulatory advice. Whether a specific product is a regulated medical device, and whether it is approved for use in Australia, should be confirmed with the vendor and a qualified adviser.

> **Two privacy laws apply in NSW** — the Commonwealth *Privacy Act 1988* (APPs) and the NSW *Health Records and Information Privacy Act 2002* (HRIP Act, HPPs). This guide is about a *different* regulator again: the TGA. General information, not legal advice.

The line that matters: admin AI vs clinical AI

There are two very different kinds of AI being sold to dental practices:

- **Admin / workflow AI** — scheduling, summarising reports, drafting copy, transcribing notes. The risks here are mostly privacy and accuracy.
- **Clinical AI** — software that **reads radiographs, detects caries or pathology, measures bone levels, screens images, or triages how urgent a patient is.** This kind of software is making, or supporting, a clinical assessment.

The second kind is where a *different* regulator can apply: the **Therapeutic Goods Administration (TGA)**.

Software can be a "medical device"

Under Australia's therapeutic goods framework, software that is intended for purposes such as diagnosis, screening, monitoring or prediction of disease can fall within the definition of a **medical device** — often called **Software as a Medical Device (SaMD)**. Medical devices generally need to be **included in the Australian Register of Therapeutic Goods (ARTG)** before they are supplied or used in Australia, and they carry obligations around their declared intended purpose and safety.

(The exact classification rules and what counts as a regulated medical device are technical and should be confirmed with the TGA or a qualified adviser — this guide flags the question, it does not answer it for a specific product.)

What to check before switching on a clinical AI tool

Before a practice relies on an AI tool that detects, diagnoses, measures or triages:

- **Is it included in the ARTG?** Ask the vendor directly and look for the ARTG number. "It's used overseas" or "it's FDA-cleared in the US" does **not** mean it is approved for use in Australia.
- **What is its declared intended purpose?** A tool approved as a "decision support" aid is not the same as one cleared to make a diagnosis. Using a tool beyond its intended purpose is a risk.
- **Who is responsible for the clinical decision?** The treating dentist remains clinically responsible for diagnosis and treatment. AI output is an input to the clinician's judgement, not a substitute for it.
- **Does it also move patient data?** Clinical AI usually sends images or records to be processed — often overseas. So the privacy questions in the rest of this library (extraction, APP 8 / overseas disclosure, HRIP) apply on top of the device question.

Why owners should care

Switching on a clinical AI tool that should have been a registered medical device, or using one beyond its approved purpose, is a regulatory exposure that sits **outside** privacy law — and it is exactly the kind of thing a busy practice adopts without asking. It is worth a short check before purchase, not after.

See Where Patient Data Is Protected — and Where It Escapes for the privacy side of the same tools.

This guide is educational material only. It is not legal or regulatory advice and does not determine whether any product is, or is not, a regulated medical device. Confirm a product's regulatory status with the vendor and the TGA, and seek qualified advice for your circumstances.