Orthopedic Device Registration in Australia

OSMA Meeting January 2025

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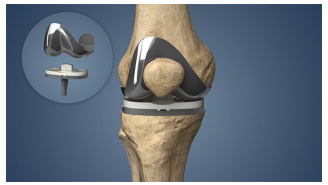
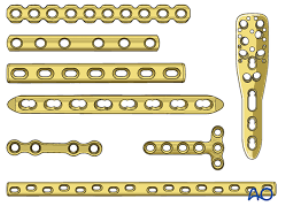
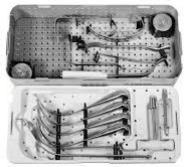
Regulatory Framework

- Requirements are generally aligned with EU MDR
- Key components:
  - Legal Manufacturer
  - GMDN
  - Class
  - Sponsor
- Prior to supply, the medical device must be included on the Australian Register of Therapeutic Goods (ARTG)

Classification Examples

DEVICE TYPE		TGA Risk Classification
Joint Implants		III
Plates and Screws		IIb
External Fixators		IIb
Instruments		I, Is, Im, IIa, IIb
Digital		IIa, IIb

Comparable Overseas Evidence

https://www.tga.gov.au/resources/guidance/use-market-authorisation-evidence-comparable-overseas-regulators-and-assessment-bodies-medical-devices-including-ivds

Leveraging Overseas Approvals

Key Considerations

1. Device must still meet the TGA Essential Principles
2. Clinical evidence is required per TGA guidance
3. TGA may conduct an application audit