Lifecycle of a Medical Device / IVD

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Examples used DO NOT imply any action or decision on the part of any sponsor, manufacturer or the TGA.
Lifecycle of a Medical Device / IVD
Example Medical Devices

Class III Medical Device
Contains human &/or animal origin material

Class I IVD Medical Device/Class IIb Medical Device
Self-testing
Pre-Market

Class III Medical Device
Contains human &/or animal origin material
Pre-Market

Clinical Evidence

Manufacturers Evidence

Approval of Conformity

Application for Inclusion

Advertising Promotion

Code

Application Audit

ARTG
Post-Market

- Clinical Evidence
- Advertising Promotion
- Market and Supply
- Complaints, Literature, user experience
- Ongoing Reports, TGA audits
- Code
- ARTG
Lifecycle of a Medical Device / IVD

- Adverse Event Reporting
- Incident/patient impact
- Clinical Evidence
- Complaints, Literature, user experience
- Market and Supply
- Ongoing Reports, TGA audits

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IMPORTANT SAFETY INFORMATION

WARNING: Do not wear sensor longer than the time indicated in these instructions for use. Doing so may cause adverse skin reactions.
Post-Market

- Notification of Change
- Re-Engineer/Reformulate
- Clinical Evidence
- Design, Develop, Validate
- Approval of Conformity

ACMD

Conformity Assessment

Approval of Conformity

Design, Develop, Validate

Clinical Evidence

Re-Engineer/Reformulate

Notification of Change

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Clinical Evidence

- Notification of Change
- Uniform Recall Procedure
- Adverse Event Reporting
- Conformity Assessment
- Design, Develop, Validate
- Approval of Conformity
- Advertising Promotion
- Market and Supply
- Complaints, Literature, user experience
- Ongoing Reports, TGA audits
- Incident/patient impact
- Product Recall/Correction
- Re-Engineer/Reformulate
- Manufacturers Evidence
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Clinical Evidence

- Notification of Change
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