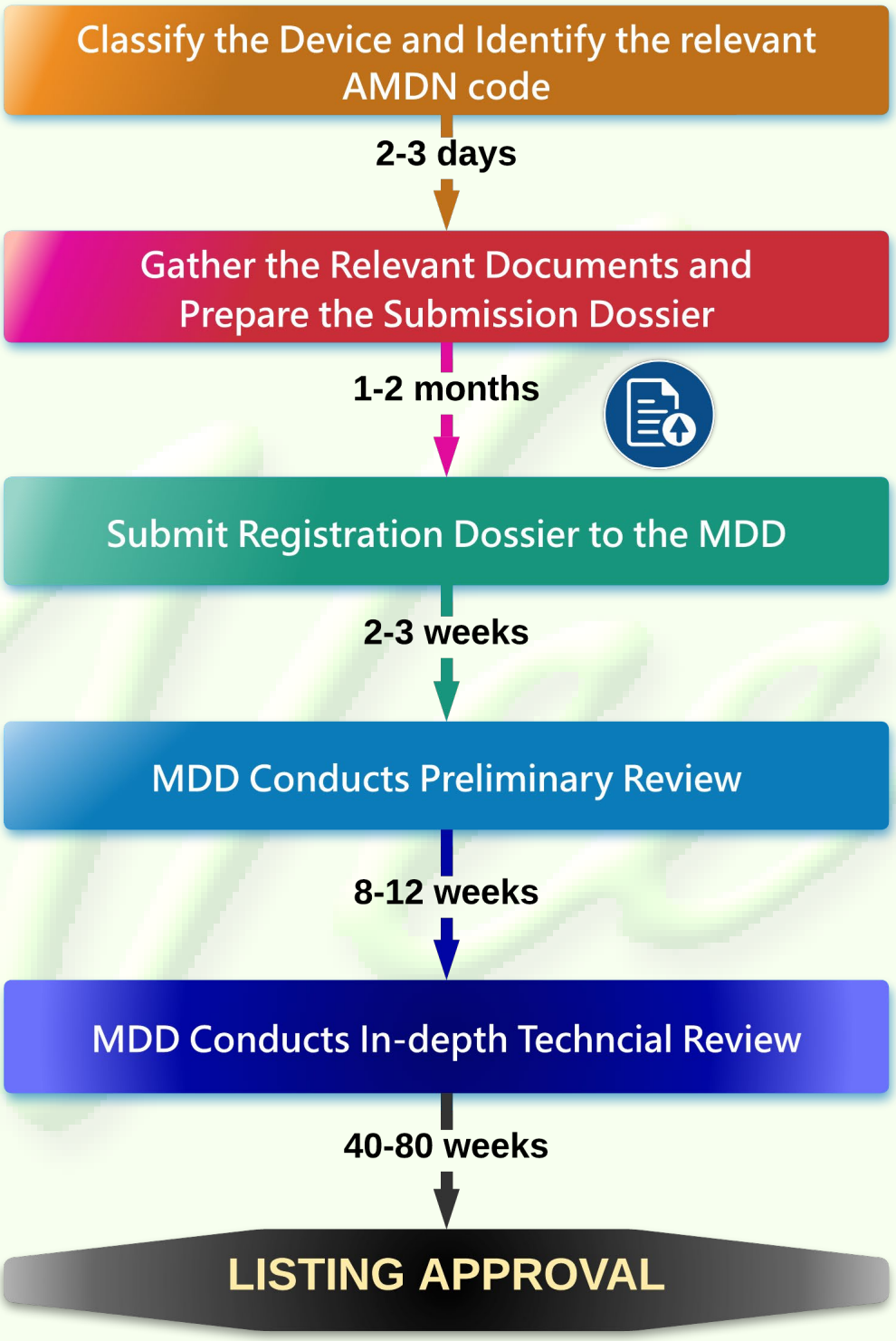
MARKET ACCESS TO HONG KONG

REGISTRATION PROCESS



MARKET ACCESS TO HONG KONG

DOCUMENTS REQUIRED

Application Requirements	Prepared by LRP	Prepared by MFR
LRP Designation Letter	✓	✓
LRP's BR	✓	
Application Form	✓	
IFU		✓
Device Labelling	✓	✓
ISO13485 (Manufacturer and Subcontractors)		✓
Marketing Approval (e.g., EC Certificate / 510k)		✓
EC Declaration of Conformity		✓
History of Recalls / Adverse Events		✓
Bench Test Report (s)		✓
Clinical Investigation / Evaluation Report		✓
Essential Principles Conformity Checklist		✓