

MARKET ACCESS TO TAIWAN



GLOBAL MEDICAL DEVICE CONSULTING



Vee VEE CARE (ASIA) LTD

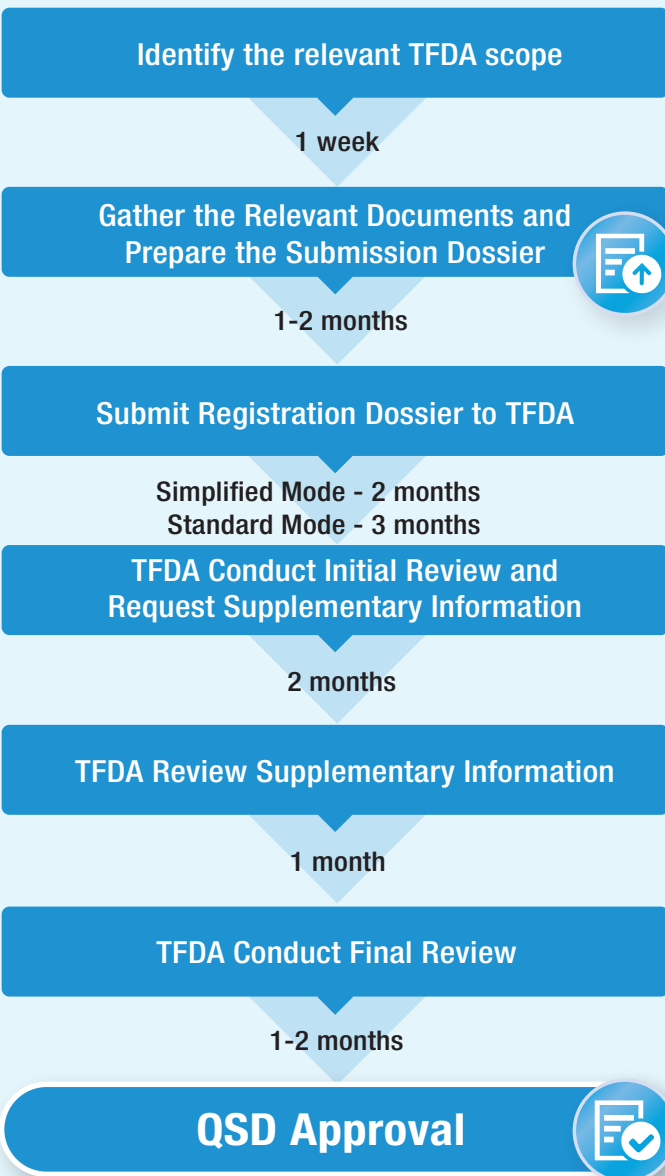


MD 653109

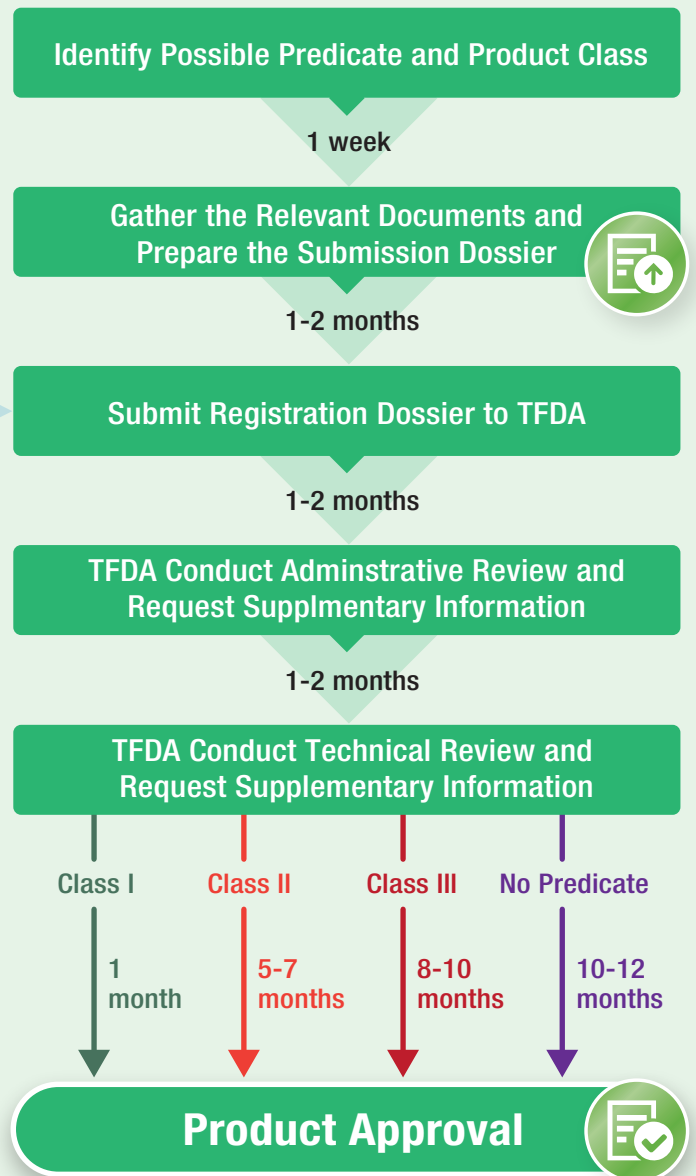


REGISTRATION PROCESS

PRODUCTION SITE REGISTRATION (QSD)



PRODUCT REGISTRATION





DOCUMENTS REQUIRED

Technical Dossier	Vee Care	Manufacturer
Information on previous applications	✓	
Predicate Information (Taiwan registration #, Chinese IFU, indication and specification comparison)	✓	
Application form	✓	
Local MD Dealer License – License Holder	✓	
Legalized Free Sales Certificate from Home Country		✓
Letter of Authorization from Manufacturer to local license holder (original copy)		✓
QSD Certificate of Manufacturing Plant		✓
Subcontractor Agreement (if any)		✓
Packaging artwork & Product Labels (2 sets)		✓
Chinese IFU / Product Manual (2 copies each)	✓	
Product Photo (representative model)		✓
Original IFU / Product Manual		✓
Product Brochure		✓
First introduction country, date, manufacturer name, site & model number		✓
Product drawing, structure, composition, materials, specification, intended use, performance, and safety data		✓
Operation Manual		✓
Maintenance Manual		✓
Radiation Safety Information (if applicable)		✓
Certificate on animal origin materials		✓
The source of animal tissue, raw material extraction process, manufacturing process and raw material quality control (if applicable)		✓
Validation on the clearance or inactivation of viruses or other infectious agents derived from animal tissue sources (if applicable)		✓
Documents in compliance with “Good Tissue Practice, GTP” (if applicable)		✓
DEHP dissolution test and risk assessment report. (if applicable)		✓
Usability evaluation report		✓
Essential requirement checklist (applicable for Class III devices)		✓
STED technical file (applicable for Class III devices)		✓
Risk management file		✓
Preclinical test protocol/report		✓
Finished product specifications, test methods & test reports		✓
Clinical evaluation report		✓
Registration certificates or FSC other than home countries		✓
Quality System Documentation	Vee Care	Manufacturer
Declaration letter for the plant information (include plant name, address, list of process done by contractors...)	✓	✓
ISO 13485 certificate		✓
Quality Manual & Procedures stated in the Manual		✓
Plant layout & detail layout of the manufacturing area		✓
Product list and Manufacturing process flowchart		✓
Major Equipment list		✓
Medical device file		✓

Vee Care provides a complete set of regulatory and compliance solutions for medical manufacturers.

Please visit our website for more information:

www.vee-med.com



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