Market Access To US (510K)

Global Medical Device Consulting

VEE CARE (ASIA) LTD

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

MD 653109

MARKET ACCESS TO US (510K)

LISTING PROCESS

FDA 510K Technical File Set Up

1-2 weeks

- Performance Validation
- Safety Validation
- Clinical Evaluation
- Risk Management
- Usability

3-6 weeks

510K Submission Dossier

1 month

Acceptance Review Completed

2 months

Substantive Review Completed or Additional Infomration required

1 - 6 months

510k Approval

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DOCUMENTS REQUIRED

- Medical Device User Fee Cover Sheet (Form FDA 3601)
- CDRH Premarket Review Submission Cover Sheet
- 510(k) Cover Letter
- Indications for Use Statement
- 510(k) Summary or 510(k) Statement
- Truthful and Accuracy Statement
- DOC and Summary Reports
- Executive Summary
- Device Description
- Substantial Equivalence Discussion
- Proposed Labeling
- Risk Management
- Sterilization and Shelf Life
- Biocompatibility
- Software
- EMC and Electrical Safety
- Performance Testing - Bench
- Performance Testing - Animal
- Performance Testing – Clinical

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

Please visit our website for more information:

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