Market Access To US (510K)

Global Medical Device Consulting

VEE CARE (ASIA) LTD

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MD 653109

MARKET ACCESS TO US (510K)

510K Notification PROCESS

FDA 510K Technical File Set Up

1-2 weeks

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

3-6 weeks

DAY 01 Manufacturer submits 510k via e-Star
FDA conducts Acceptance Review **And**

DAY 15 FDA conducts Substantive Review
Place on RTA Hold [Max.180-Day] **OR**

DAY 60 FDA proceeds with Interactive Review Place On hold for Additional Information [Max.180-day] **OR**

DAY 90 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 and Cybersecurity
- EMC and Electrical Safety
- Performance Testing - Bench
- Performance Testing - Animal
- Performance Testing – Clinical

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