CONSULTING SERVICES

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Product Research & Development: Design engineering, design control, material review, DHF/DMR/DHR development,concept development, packaging design, and packaging development

Preclinical & Clinical Testing: Raw materials testing, reliability testing, analytical testing, biocompatibility testing,and assessment

Clinical Research/Clinical Affairs: Biometrics, clinical operations, clinical systems, and medical affairs

Submission & Registration: 510(k), PMA, IDE, CE mark, labeling, design dossier, and due diligence for bothmedical and combination devices

Post-FDA Approval Production & Comprehensive Packaging: Packaging design, product transfer, manufacturing, sterilization, quality engineering,automation, lean manufacturing, Six Sigma, PFMEA, and facilities expansion

Validation: Cleaning, Master Validation Plans (MVP), equipment, process, computer systems,packaging, shelf life, test method, and sterilization

Quality Engineering & Quality Assurance: QMS development, SOPs, audits, remediation management, CAPA, suppliermanagement, warning letter responses, 483 responses, consent decree consultationand solutions, inspections, complaint handling, complaint review, document control,medical device reporting (MDR), post-market monitoring and surveillance, productrecall, change control, and device EOL management

Facilities Compliance & Expansion: Facility and utilities design, set-up, inspection, construction management, facilityand equipment commissioning, HVAC, manufacturing environment, cleanroom, andcost control

Technology Transfer & Collaboration: Training, knowledge, and document management, from design to production

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