THE PREMARKET APPROVAL (PMA) PROCESS

EXPERTISE SUPPLY DEMAND Investigational Device Exemption (IDE) Approval **NETWORK OF EXPERTS** (for general knowledge sharing) Confirmation of development plan with FDA Clinical Trials PANEL OF SPECIAL GOVERNMENT EMPLOYEES Submission of PMA Approximately 90 days to convene **FDA Review** APPLICANT FIRM Request for more information by FDA **OPTIONAL** PANEL OF SPECIAL GOVERNMENT EMPLOYEES **FDA Review** FDA Approval Decision **10-15 INTERNAL FDA STAFFERS** Convened by the Office of Device Evaluation in an ad hoc process Lead Reviewer **ODE Branch Chief** 1-2 Medical Officers 1 Statistician 1 Epidemiology Reviewer 1-2 Biocompatibility Experts 1 Packaging and Sterility Expert 3-4 Engineers 1 Manufacturing Expert