Stages	Activity	Responsibility	Duration
Step 01	Identify the device	Client	7 Days
Step 02	Identify the models and variants.	Client	
Step 03	Appoint consultant.	Client	
Step 04	Determination of Intended use	Client	45-90 Days
Step 05	Identify of product code and Regulation Number.	Consultant	
Step 06	Identify Predictive Device.	Consultant + Client	
Step 07	Get device Guidance from FDA	Consultant	
Step 08	Determination of 510(k) Type	Consultant	
Step 09	Content creation for Traditional or Abbreviated 510k	Consultant	
Step 10	Identify national and international standards	Consultant + Client	
Step 11	Suitability of Documents related to stability Biocompatibility and sterilization	Consultant + Client	
Step 12	Identify test requirements.	Consultant	
Step 13	Certification and summery	Consultant + Client	
Step 14	Prepare Submission File. (510 k Notification)	Consultant + Client	
Step 15	Label review	Consultant	
Step 16	Product Testing	Client	
Step 17	Appoint US Agent (Foreign manufactures)	Client	NA
Step 18	FDA Review Fee Payment	Client	5 Days
Step 19	Notification Submission to FDA	US Agent + Consultant	14 Days
Step 20	Coordinate with FDA Reviewer	US Agent + Consultant	60-180 days
Step 21	Q- Submission/ Pre Submission if more comments	Consultant + Client	30 Days
Step 22	Supplementary Document Submission if requested by FDA	Client	Based on availability
Step 23	Establishment Registration Fee payment to FDA	Client	5 Days
Step 24	Establishment Registration	US Agent + Consultant	7 Days
Step 25	Device Listing	US Agent + Consultant	