Data Development Plan Example 1

This is an example approach for how the Data Development Plan information recommended in the EAP guidance could be organized.

Device Name: <device name>
Sponsor: <sponsor name>

Section 1: Proposed Balance of Premarket and Postmarket Data Collection (if applicable) <(for PMA devices only) explanation and justification for proposed balance of premarket and postmarket data collection including a description of the type of data to be included in the PMA (*Example: surrogate endpoints*) and a discussion of the relevant benefit-risk information>

Section 2: Data Collection Plan.

Device Description. <an overview of the product including principles of operations (including components) and properties relevant to clinical function, if known; please include images as appropriate>

Proposed Labeling. <high-level proposed labeling including intended use/indications for use>

The table below does not create new requirements or expectations for affected parties, nor is this table intended to convey FDA's recommended approaches or guidance. Rather, this table is an example of how the Data Development Plan information recommended in the EAP guidance could be organized.

Non-Clinical Testing		
Test	**Reference standard, method, acceptance criteria, objective, etc.**	**Timeline (when testing results will be provided to FDA)**
<test name/type. *Example: Electromagnetic Compatibility, Biocompatibility, Sterilization, Mechanical Fatigue testing, Animal Study, Address Disapproval Concerns #1-10 in FDA's G160001 letter dated 1/31/2016*	<relevant standard, description of method, acceptance criteria, objective, etc. to describe testing expectations. *Example: IEC 60601-1-2; cytotoxicity, sensitization and irritation testing per ISO 10993; Assess operability of device; See Disapproval Concern language*>	<when test results should be provided to FDA. *Example: In Feasibility Study IDE, In Pivotal Study IDE, In Marketing Application, or Post Approval*>

Clinical Study: <Clinical study type; note that **this table should be repeated for each clinical study required**; *Example: Early Feasibility, Feasibility, Stage I Pivotal, Stage II Pivotal, Pivotal, Post Approval*>	
Purpose	<purpose of study. *Example: To demonstrate basic safety and proof of principle for XXXXX device; To demonstrate superiority to control with respect to surrogate endpoints; To confirm adequacy of surrogate endpoints in prediction of mortality and morbidity benefit*>
Study Design	<study design information. *Example: Single center, nonrandomized; multi-center randomized, double blinded*>
Study Population	<study population, which should align with indications for use requested. *Example: Patients with upper extremity and lower extremity spasticity secondary to stroke who meet all study inclusion criteria and none of the study exclusion criteria*>
Sample Size	<sample size. *Example: 10 control, 20 treatment; to be determined pending effect size from feasibility study results*>
Inclusion Criteria	<inclusion criteria. *Example: Patients over 18 years of age, on optimal medical therapy, and who have had symptoms for >3 months; to be determined pending feasibility study results, but will align with requested indications for use*>
Exclusion Criteria	<exclusion criteria. *Example: Patients eligible for physical therapy or surgery, unable to provide consent, enrolled in clinical study for same condition; to be determined pending feasibility study results, but will align with requested indications for use*>
Safety Endpoints	<safety endpoints. *Example: No statistically based safety endpoint, but the below adverse events will be captured; Treatment related adverse events as defined below < 30%*>
Effectiveness Endpoints	<effectiveness endpoints. *Example: No statistically based effectiveness endpoint, but the following parameters will be captured; Patient success defined as improvement of >/= 2 points in below QOL scale and study success defined as >75% patients meeting success criteria; To be determined based on effect size estimates from feasibility study*>
Follow-up Schedule	<follow-up schedule. *Example: Subject participation will last approximately 4 weeks as indicated below, adverse events will be captured throughout study- Week 1: enrollment, informed consent, baseline assessment, Week 2- procedure, Week 3- electrical parameter collection and QOL assessment, Week 4- electrical parameter collection and QOL assessment, study exit. To be determined based on feasibility study results*>

Section 3: Timeline. The below list outlines key time points for the development and marketing of the device as well as (if applicable) for the postmarket data collection.

<key milestones and time points. *Example:*

- *Device development and nonclinical safety and performance testing: Q1 2017*
- *Submission of IDE for early feasibility study (EFS): Q3 2017*
- *Conduct EFS: Q4 2017*
- *Submission of IDE for pivotal clinical study: Q1 2018*

- *Conduct pivotal clinical study: Q2 2018*
- *Prepare and submit marketing application: Q4 2018*
- *Begin Post Approval Study: Q5 2018*
- *Post Approval Study completion: Q1 2020*>