PRA Question Fields for Q-Sub SMART

Withdrawal

* Reason for withdrawal? (Compiling the Administrative File for Premarket Submission Decisions SOP)

Accessory Classification Eligibility Review (“Medical Device Accessories – Describing Accessories and Classification Pathways” Guidance Document)

* Was request included in PMA or 510(k) of parent device?
* Has accessory been previously classified?
* Is applicant a manufacturer/importer of device via PMA, 510(k), or De Novo?
* Is article a finished device?
* Is device intended to be used with one or more parent device(s)?
* Does device support/supplement/augment performance of parent device?

Breakthrough Designation (§ 515B of the Food, Drug, and Cosmetic Act, and “Breakthrough Devices Program” Guidance Document)

* Is device subject to PMA/De Novo/510(k)?
* Will device provide for more effective treatment or diagnosis of life threatening or irreversibly debilitating human disease or conditions?
* Does device meet one of these criterion: breakthrough technology, no approved/cleared alternative, offers significant advantages over existing alternatives, or availability is in the best interest of patients?
* Was patient perspective information considered in determining whether the designation criteria were met?

STeP Eligibility (“Safer Technologies Program for Medical Devices” Guidance Document)

* Is device subject to PMA/De Novo/510(k)?
* Is device ineligible for Breakthrough?
* Is device expected to meet at least one of the following safety innovations: reduce occurrence of serious adverse event, reduce occurrence of device failure mode, reduce occurrence of use-related hazard or use error, improve safety of another device or intervention?
* Is product a device-led combination product?

Submission Characteristics

* Will future marketing pathway likely be PMA, De Novo, HDE, or Expedited 510(k)? (Not requested of sponsor, reviewer only)
* How many consults from outside Center? (Not requested of sponsor, reviewer only)
* How many questions posed by applicant? (Not requested of sponsor, reviewer only)
* Will feedback be sent to applicant which goes beyond questions asked? (Not requested of sponsor, reviewer only)
* Did applicant submit a DDP? (Not requested of sponsor, reviewer only)
* Did applicant request feedback that will be reviewed as future supplement? (Not requested of sponsor, reviewer only)
* Is applicant OUS? (Not requested of sponsor, reviewer only)
* Is device a combination product? (“Requests for Feedback and Meetings for Medical Device Submissions: The Q-submission Program” Guidance Document)
* What type of expedited programs interaction is requested? (Not requested of sponsor, reviewer only)
* Was agreement on DDP reached? (Not requested of sponsor, reviewer only)
* Will tracked changes version of DDP be provided via email? (Not requested of sponsor, reviewer only)