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)