Physiological Monitors Issues in human testing requirements for FDA submissions 510k and de Novo

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Physiological Monitors
Issues in human testing requirements for FDA submissions
510k and de Novo

Agenda

Examples: Pulse Oximetry & Blood Pressure

Standards, Guidance Documents & Non-Public Knowledge

Old Approach / New Approach

Pre-Submission How-to & Additional Support

When to Submit

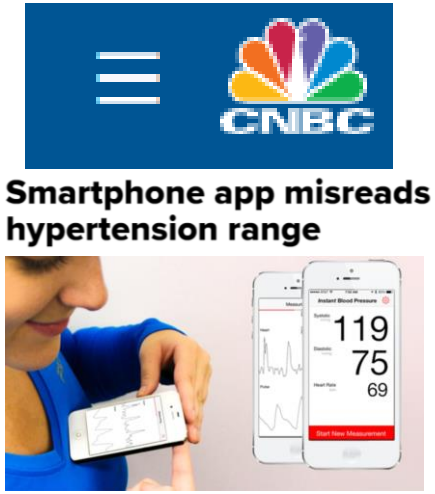
When to Test

Human Factors

Example – Pulse Oximeter

- New Application: Predicate
- Significantly Different Technology: Only Mobile Phone or Tablet
- Significantly New Populations: Wearables
- Significant change or new information in medical knowledge

Example – Blood Pressure



- Significantly Different Technology: No pressure transducer - De Novo
- New test methods required: Learning Process - Pre-Submission?
  - ISO Blood Pressure test for cuff-based devices
  - Combination of IEEE & ISO & Non-Public Knowledge for PPG

Standards, Guidance Documents, & Non-Public Knowledge

- 510k: Predicate Device
- De Novo: No Predicate –
- Recognized Standards
- Guidance Document
- New technology, new application, Pulse Oximetry: Guidance Difference from ISO
- Blood Pressure: Recognized Standard (Partial), New Technology – FDA is exploring & learning
- Non-Public Knowledge is information recently learned by the Reviewers that is not in a Guidance Document or in a Standard

Old Approach : New Approach

- Technology is Changing Rapidly as are Accuracy Test Methods: Often Standards are struggling to keep pace
- Often the FDA requires unpublished methods and acceptance criteria that is based on new information
    - BP Changes & How, Number of Sites
- Old paradigm: treat as a contentious legal situation – only say the minimum
- New Approach: collaborative, interactive (don’t break into jail, but positive interaction is helpful)
- If the device fits a *Recognized Standard* exactly, then proceeding with a 510k may be warranted

Pre-Submission – How To

- FDA, and thus the Reviewers, are eager to interact
- Pre-Submission is the avenue

- Never ask how to test; instead provide a solution and ask if the FDA agrees; always include additional options in the Pre-Sub documentation
  - If they do not agree, immediately go to your next option
- Always include accuracy acceptance criteria
- Be certain the Accuracy test method is actually measuring the accuracy of the technology
  - A PPG based device can pass the ISO BP test for a cuff even if the device does not detect changes in blood pressure

Pre-Submission – Additional Support

- Reviewers Invite Interaction
- Don’t break into jail, but positive interaction is helpful
- During all live interactions you must have a seasoned regulatory specialist to direct traffic
- Do not overwhelm the FDA with large numbers of speakers
- Start with the most important issues
- Peer Reviewed Publications are effective
- Expert panels are minimally helpful and will not sway FDA opinion, especially if the acceptance criteria are not met
- All of this assumes the device meets FDA acceptance criteria

When to Submit to the FDA

- Pre-Submissions may be submitted prior to conducting the Pivotal Trial and are advised with the following:
  - New technology type
  - Significant change or new information in medical knowledge
    - New or updated Standard
    - Findings that bring technology accuracy into question
    - De Novo (no Predicate Device)

When to Test for Accuracy

- The most common factor that delays clearance in physiological monitors is the lack of accuracy testing early in the development process
  - Often FDA submissions are initiated prior to knowledge of accuracy performance
    - Including Accuracy testing as a gating item in the schedule during development is crucial
  - Test Early and Often

Human Factors / Usability

Applying Human Factors and Usability Engineering to Medical Devices

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Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016

- Human Factors: Guidance document –
- Highest on list are invasive and life support
- However, new apps (phone, tablet, etc.) may result in the user/patient changing medication or could provide info that would discourage the user/patient from contacting their Physician

Q&A

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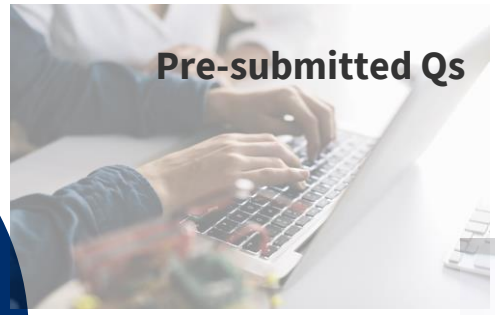

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