AdvaMed
Advanced Medical Technology Association

Replacement Reagent and Instrument Family Policy
Recent Experiences in Submissions

FDA-Industry IVD Roundtable Meeting

Ann Quinn, Ortho-Clinical Diagnostics
AdvaMed Diagnostics Task Force

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

November 18, 2014

Outline

AdvaMed
Advanced Medical Technology Association

- Overview/Industry Support
- Background
- General Comments
- Areas of Concern/Clarification
- Recent Submission Experience
- Recommendations

Industry Support

AdvaMed
Advanced Medical Technology Association

– Support this critical FDA policy

- Previously cleared instruments and reagents, when a claim is made for a new reagent/instrument combination
- Introduction of new instrument family members of a previously cleared instrument family

Background

AdvaMed
Advanced Medical Technology Association

- FDA longstanding policy
  - Reduce redundant submission requirements for previously characterized laboratory systems
  - Use of acceptable test system validation protocol
- Well integrated with quality system—all documentation on file

Background

AdvaMed
Advanced Medical Technology Association

- Not in scope
  - Changes that could significantly affect the device's safety or effectiveness
  - Class III devices
  - Systems intended for OTC, POC or professional home use
  - Devices intended for use in blood banking practices
  - Exempt general purpose reagents

General comments

AdvaMed
Advanced Medical Technology Association

- Recent experiences in submissions
  - Inconsistent interpretation/application and non-recognition of policy
  - Unclear rationale or none provided for change; appears somewhat subjective
- Not well aligned with objectives of guidance
- Highlight need for discussion and clarity
- Changes to longstanding FDA policy or thinking? Branch differences?

Exs of Some Areas of General Concern, Further Clarification

AdvaMed
Advanced Medical Technology Association

- Imposing requirement for reconduct of all identical studies for the original 510(k) on the new family member
- Exclusions for additional tests on ad-hoc basis beyond outlined exceptions in guidance
- Narrowed interpretation of “family member”
- Confusion in industry; Lack of clarity on applicability of policy.

Recent Submission Experience

AdvaMed
Advanced Medical Technology Association

Imposing requirement for reconduct for all identical studies for the original 510(k) on the new family member

- Yet policy provides that a justification may be provided on why the study is not necessary
- Studies being requested that are related to assay design and methodologies and are not instrument driven (e.g., specimen tube type study, interference study)

Recent Submission Experience

AdvaMed
Advanced Medical Technology Association

Exclusions for additional tests on ad-hoc basis beyond outlined exceptions in guidance

- Notified during submission process that RRIFP policy no longer eligible for "X" test
- Policy appears to be limited to case-by-case basis
  - What is the specific criteria for exclusion?
  - Can exclusions be clearly outlined for industry along with scientific rationale?

Recent Submission Experience

AdvaMed
Advanced Medical Technology Association

Narrowed interpretation of "family member"

– Previous decisions on family members are no longer deemed applicable

What Can We Do

AdvaMed
Advanced Medical Technology Association

- Encourage open dialogue
- Work together to support understanding of policy
  - Support consistency in application
  - Relay any changes in thinking to policy
  - Clearly communicate any exclusions and specific criteria on overall basis
  - Care not to impose redundant testing—which undermines this important longstanding policy
- Support overall diagnostics regulatory process

AdvaMed

Advanced Medical Technology Association

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE