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Blood Glucose Meter Disinfection
Facilitating the Process Moving Forward

FDA-Industry IVD Roundtable Meeting

Alan T. Cariski, MD, JD
AdvaMed BGM Working Group

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

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Outline

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- Introduction
- Background
- Considerations
- Recommendations
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Introduction

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- Industry commitment
  - Design and manufacture blood glucose meters that meet the needs of individuals with diabetes
  - Foster communication and understanding of FDA expectations
  - Support overall process that promotes public health and timely access to important technologies

Background

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- Public Health Notification re. shared device use and risk of viral hepatitis B (8/10)
- Notice to Industry Letter distributed to BGM Manufacturers Listed with FDA (9/10)
  - New requirements immediately into effect--current and future submissions
- Extensive industry efforts to work with FDA and testing labs to validate cleaning and disinfection procedures and to ensure robustness

Considerations

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- Collaborate to leverage understanding of what works
- Promote consistency and transparency in study design and expectations
- Utilize an FDA-accepted protocol
- Assure clear and efficient process for validating these procedures
- Facilitate timely review and overall regulatory process

Recommendations to Support Process

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- Provide copy of protocol and summary of results for special 510(k) submission
- Use of accepted protocol for validation of additional disinfectants and document in design history file
- Use of accepted protocol for additional devices and document in design history file
- Provide rationale for qualification when material is previously qualified

Next Steps

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- Welcome FDA's efforts to discuss with industry and share current thinking (e.g., IVD Roundtable)
- Encourage continued collaboration and opportunity for comments
- Issue draft guidance as an important priority
- *Appreciate FDA's support to consider ways to facilitate timely review and overall process*

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