Blood Lancets – Safety Issues Office of Device Evaluation Center for Devices and Radiologic Health

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Blood Lancets – Safety Issues

Blood Lancets are:

- Pre-Amendment Devices
- Classified as Manual Surgical Instruments
- Regulated as Class I exempt devices since 1994
- Previously Class II devices

Blood Lancets – Safety Issues

- As blood-drawing devices, blood lancet blades should be used only once and safely discarded
- If used on more than 1 patient, lancet blades can transmit bloodborne pathogens such as Hepatitis B and C and HIV
- Reusable lancet device bases can contaminate serial lancet blades

Blood Lancets – Safety Issues

- 8/26/2010 CDC and FDA issued safety communications warning that the use of blood lancet devices on more than 1 patient has transmitted hepatitis B and C

- 8/27/2010 CMS issued a Survey Memorandum on POC testing for Nursing Homes listing the use of lancet devices on more than 1 patient as an IC Deficiency

Blood Lancets – Safety Issues

11/30/2010 – FDA "Guidance for Industry and FDA Staff: Blood Lancet Labeling"

- Recommended that all blood lancet devices be labeled for use only on a single patient
- Recommended that lancet devices capable of multiple uses be labeled for single use only and labeled that they should not be used for assisted blood draws by healthcare personnel

Blood Lancets – Safety Issues

Current Concerns About Blood Lancet Safety

- FDA does not review Lancet labeling
- FDA does not review Lancet performance
- FDA is not certain that all devices comply with Registration and Listing requirement
- The 2010 Blood Lancet Guidance addresses only labeling, not performance issues

Blood Lancets – Safety Issues

Current Concerns About Blood Lancet Safety

- Some Older Blood Lancets Were Labeled for Use in More than 1 Patient
- Not All Healthcare Staff Are Aware of the Risk of Sharing Blood Lancets
- Some Healthcare Facilities Have Provided Multiple Use Capable Lancets for Staff Use

Blood Lancets – Safety Issues

Current Concerns About Blood Lancet Safety

- Neither FDA Nor CDC Regulates the Practice of Medicine
- Regulatory Entities May Need More Than Labeling Guidance to Support Action

Medical Device Classification

Class I -93% are 510(k) Submission Exempt

General Controls

Class II – 9% are 510(k) Submission Exempt

General Controls & Special Controls

Class III – Premarket Approval - Safe & Effective

General Controls

General Controls for Medical Devices

- Adulteration/Misbranding (Labeling)
- Electronic Device Registration & Listing
- Premarket Notification 510(k) Submission
- Quality Systems
- Labeling
- Medical Device Adverse Event Reporting

Special Controls for Medical Devices

Special Controls Guidelines requirements may include:

- Performance Testing
- Consensus Standard Compliance
- Special Labeling Requirements

Medical Device Guidance

FDA also publishes general guidance documents for devices of all classes. These guidance documents are not “Special Controls”, but their recommendations should be addressed in premarket submissions

Premarket Notification 510(k) Submission

- Premarketing clearance process
- Demonstration of “Substantial Equivalence” (SE) to legally marketed device
- SE means “At least as safe and effective”

Premarket Approval Application

- Pre-Marketing Approval
- Demonstration that device is safe and effective
- Clinical study often necessary

Blood Lancets – Safety Issues

FDA Options to Improve Device Safety

- Labeling Guidance
- Special Labeling
- Special Controls Guideline
- Change Device Classification
- Special Regulations i.e. Latex Caution Label, Maximum Acceptable Ozone Level