

Brief Summary of the General and Plastic Surgery Devices Panel Meeting June 26, 2013

Introduction:

The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on June 26, 2013 to make recommendations regarding the possible reclassification of blood lancet devices. The Panel discussed whether new scientific data are sufficient to support the reasonable assurance of safety and effectiveness to develop special controls that support regulation of blood lancets from class I to class II and class III. FDA identified the following four subsets of blood lancets used to puncture skin to obtain a drop of blood for diagnostic purposes:

- (1) A single use only blood lancet with an integral sharps injury prevention feature;
- (2) A single use only blood lancet without an integral sharps injury prevention feature;
- (3) A multiple use blood lancet for single patient use only; and
- (4) A multiple use blood lancet for multiple patient use.

Panel Deliberations/FDA Questions:

The panel was asked to comment on the following risks to health:

- Bloodborne pathogen transmission due to lancet misuse
- Sharp object injuries
- Local skin infections
- Adverse skin reaction (not infection)

The panel believes that the list is complete and that nothing should be removed but concerns were raised about misuse and some information about the severity of the risks could be added.

The panel agrees that general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness for any of the four types of blood lancets.

The panel believed that these devices are not “life-supporting or life-sustaining, or of substantial importance in preventing impairment of human health.” However there were some concerns over the fact that they are an integral component of preventing impairment of human health in diabetic patients.

The panel generally agreed that the risks and benefits of the devices, when used for single patient use only do not present a “potential unreasonable risk of illness or injury”.

The panel agrees that the following special controls were adequate to provide reasonable assurance with an emphasis on visible labeling:

- i. Labeling
- ii. Biocompatibility testing

- iii. Sterility of the lancet
- iv. Performance testing including verification of design characteristics and include cleaning/disinfection validation as appropriate (for multiple use in a single patient)

The panel believed that the special controls as listed are adequate however attention needs to be directed to the labeling. Current labeling should emphasize single patient use and for those devices without sharps disabling capabilities, they should have instructions for proper disposal.

Considering the risks and benefits of these devices, the panel believed that blood lancets when used for multiple patient use does present a “potential unreasonable risk of illness or injury”.

The panel agreed that there are no special controls that would be sufficient to mitigate the risks to health and provide a reasonable assurance of safety and effectiveness of multiple use blood lancets for multiple patients.

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