



Brief Summary of the Clinical Chemistry and Clinical Toxicology Devices Panel Meeting July 21, 2016

Introduction:

The Clinical Chemistry and Clinical Toxicity Devices Panel met on July 21, 2016, to discuss, make recommendations and vote on information regarding a premarket approval application (PMA) panel-track supplement, for a proposed change in intended use of Dexcom, Inc.'s, Dexcom G5 Mobile Continuous Glucose Monitoring System (CGM) device. The proposed indications change was that, in addition to tracking and trending interstitial fluid glucose concentrations, patients could use the device as a replacement for their blood glucose meters and make diabetes treatment decisions based on the glucose concentrations and trend information reported by the CGM.

Deliberations:

1. Modeling

The panel discussed whether the clinical Dexcom G5 Mobile CGM accuracy studies conducted by the sponsor, and computer modeling based on these clinical accuracy studies, was adequate to provide reasonable assurance of safety and effectiveness for the proposed indications for use for the Dexcom G5 Mobile CGM System. The majority of the panel members concluded that the totality of the supporting evidence (computer modeling, clinical accuracy study data, human factors studies, and existing experience with the device on the market), was adequate to provide reasonable assurance of safety and effectiveness for the proposed indications for use for the Dexcom G5 Mobile CGM.

2. Human Factors

The panel discussed whether users would know how to safely incorporate Dexcom G5 Mobile CGM System glucose trend and rate of change information when making insulin dosing decisions. The panel concluded that the sponsor should be able to provide sufficient information in their device labeling to inform users' insulin dosing decisions using glucose trend and rate of change information. The panel did not believe that a training requirement for the Dexcom G5 Mobile CGM System should be necessary to ensure that users could safely incorporate Dexcom G5 Mobile CGM System glucose trend and rate of change information when making insulin dosing decisions. Finally, the panel concluded that the sponsor should provide additional training materials in their device labeling to ensure that providers and all user sub-populations would have sufficient information to safely and effectively use the Dexcom G5 Mobile CGM System's glucose trend and rate of change information for the proposed indications for use.

Vote:

1. The Panel voted 8-2 (with no abstainers) that there was reasonable assurance that the Dexcom G5 Mobile Continuous Glucose Monitoring System is safe for the proposed indications for use.
2. The Panel voted 9-1 (with no abstainers) there was reasonable assurance that the Dexcom G5 Mobile Continuous Glucose Monitoring System is effective for the proposed indications for use.
3. The Panel voted 8-2 (with no abstainers) that the benefits of the Dexcom G5 Mobile Continuous Glucose Monitoring outweigh the risks of the Dexcom G5 Continuous Glucose Monitoring System for the proposed indications for use?

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