Discussion questions

1. Modeling
   Please discuss whether the clinical accuracy studies, and modeling based on these clinical accuracy studies, is adequate to provide reasonable assurance of safety and effectiveness for the proposed indications for use for the Dexcom G5 Mobile Continuous Glucose Monitoring System. If not sufficient, please discuss the following sub-topics:

   a) If the modeling is insufficient, as conducted, but would if conducted adequately would provide reasonable assurance of safety and effectiveness for the proposed indications for use for the Dexcom G5 Mobile Continuous Glucose Monitoring System, what deficiencies in the conducted modeling are evident (e.g. modeling methodology, modeled use and/or physiological scenarios, modeled populations)?
   b) If modeling would be insufficient, alone, even if conducted adequately, what type(s) of study(ies) would be sufficient to provide reasonable assurance of safety and effectiveness for the proposed indications for use for the Dexcom G5 Mobile Continuous Glucose Monitoring System?

2. Human Factors
   Please discuss whether users will know how to safely incorporate Dexcom G5 Mobile Continuous Glucose Monitoring System glucose trend and rate of change information when making insulin dosing decisions. If you do not believe that users will know how to safely incorporate Dexcom G5 Mobile Continuous Glucose Monitoring System glucose trend and rate of change information when making insulin dosing decisions, please discuss the following sub-topics:

   a) What information would users require to safely incorporate Dexcom G5 Mobile Continuous Glucose Monitoring System glucose trend and rate of change information when making insulin dosing decisions?
   b) Would a training requirement for the Dexcom G5 Mobile Continuous Glucose Monitoring System allow users to safely incorporate Dexcom G5 Mobile Continuous Glucose Monitoring System glucose trend and rate of change information when making insulin dosing decisions, and if so, what type of training is recommended?
   c) If, for the general population, the risk to safe and effective non-adjunctive use may be mitigated by information provided in 2 a) and/or training provided in 2 b), above, are there any user sub-populations for which these mitigations would not sufficiently reduce risk to safe and effective non-adjunctive use (e.g. pediatric users, newly-diagnosed users)?