Software Precertification Pilot Program: Next Steps towards a Pre-Cert 1.0

The FDA anticipates public comment on the regular updates we issue.

U.S. FOOD & DRUG ADMINISTRATION

Build – Test – Iterate				Integrate – Simulate – Pre-launch			Launch
2018	Late April	Late May / Early June	Mid July	Mid August	Mid September	Mid October	December
Pre-Cert Components	Working model - Initial	Update	Update	Update	Update	Update	
Excellence Appraisal	• Excellence Principles – Objective indicators that demonstrate company-level commitment to creating safe and effective software as a medical device (SaMD) • Evaluation Method – How activities are evaluated for sufficiency • Success Criteria – How companies pass, fail, lose, and retain Pre-Cert status • Program Acceptance – How companies qualify for and initiate evaluation, including precertification levels			• Scenario Testing: Reveal the degree to which program objectives are achieved, as well as lessons learned, in order to iteratively improve the components and the whole • Finalize Pre-Cert 1.0: Integrate stakeholder feedback, lessons learned, and other input, into a cohesive set of deliverables			• **Pre-Cert 1.0** (First version of the program) • Program next steps for 2019
Review Determination	• SaMD Risk Categorization – How the Pre-Cert program treats SaMD risk categories, including alignment to other frameworks such as IMDRF • Review Process – How FDA determines categorization, how categorization may change, triggers for re-evaluation, etc.						
Streamlined Review	• Review Process – Define streamlined processes for receipt, evaluation, and determination of safety of efficacy for SaMD products from Pre-Cert companies • Postmarket Modifications – Define a system to handle product modifications, how companies demonstrate safety and efficacy of modifications, etc.						
Real World Performance	• Performance Data Elements – Real world data elements to support clinical and performance claims for safety and effectiveness • Data Capture Methodologies – How evidence is collected and made available to FDA for review • Review Process – Methodology to evaluate real world performance data for precertified SaMD organizations • Inputs to Precertification – Thresholds and triggers for modifications to precertification status • Product Claim Modification Process – Framework for use of real world data in product claim justification or modification						

This Pilot Program is an important first step to help us explore and evaluate the program model to inform how we establish the Precertification Program. Once we determine the elements for a future Precertification Program, we will then consider appropriate mechanisms for establishing the program, including FDA's current statutory and regulatory authorities.