CRISPly ? A development methotology supporting FDA approval for machine learning enabled medical devices

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Abstract

The Food and Drug Administration (FDA) has published draft guidance on a Predetermined Change Control Plan (PCCP) to enable medical device manufacturers in the release of active learning AI/ML- enabled medical devices. In this paper, we present a sophisticated process to support the implementation of this plan. Building up on the Cross-Industry Standard Process for the development of Machine Learning applications with Quality (CRISP-ML(Q)), we have developed an approach that a manufacturer can use to identify and evaluate changes to the AI/ML model. Based on the process results one can determine the impact of the modifiaction to the AI-ML Model and a the likelihood of FDA approval can be derived.

Keywords

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