Cover Page for Statistical Analysis Plan

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Statistical Analysis

The definition of post-operative ileus is "the presence of emesis, need for nasogastric intubation, or reversal of the diet beyond 24 hours from the completion of surgery". As the goal of the first phase of this trial is to optimize the device for predicting ileus, we will be maximizing the performance of the device through measurement of sensitivity, specificity, positive predictive value, negative predictive value, AUC, and accuracy of the device for each 10-20 patients (dependent upon the incidence of ileus in each group). The device performance will be compared to the surgeon prediction of ileus development, which will be assessed within the first 24 hours after surgery. The threshold for use in the second phase (validation phase) will be chosen to maximize sensitivity while maintaining the highest possible specificity. Ultimately, device performance will be considered successful if sensitivity higher than that of surgeons can be achieved for predicting ileus.