Prepare a FDA 510(k) Submission for a New Tissue Retractor Design Used in Breast Surgery

Overview
The Flapjack Tissue Retractor device is a single, self-retracting system made from biocompatible Nylon 12 which is available in various sizes meant to be used in breast surgery. The device consists of an integrated spring mechanism and protrusions which is indicated for retraction of tissues through opposite supportive forces enabling surgical access. The Flapjack Tissue Retractor is intended for use in surgical procedures where manual tissue exposure and retraction are required. In order to be used throughout the United States, it must be submitted to the FDA through a premarket notification known as a 510(k) for clearance.

Objectives
The objective of this project was to prepare and compile all necessary sections for a 510(k) submission for the Flapjack Tissue Retractor, proving that it is substantially equivalent to a predicate device that has been formerly or is currently legally marketed.

Approach
• The team learned the general information of the device and the project needs from their sponsor, Barry Fell
• Similar tissue retractor devices to the Flapjack were researched to discover true predicate devices
• A sample 510(k) was analyzed to understand each specific section and writing technique
• The team evenly distributed the sections of the 510(k) among themselves
• Individual sections were sent to the team’s sponsor for editing and feedback
• The team went back and made these corrections to create the best possible 510(k)
• The edits to the 510(k) were further validated by the team’s sponsor to ensure the submission is suitable for FDA submission

Outcomes
• This project offers the Penn State College of Medicine a viable 510(k) submission for the Flapjack Tissue Retractor that can be sent to the FDA
• The team was able to save stakeholders months of research and writing about the Flapjack and its predicate device
• The Flapjack will potentially be cleared by the FDA within 90 days of the official 510(k) submission which allows surgeons to get access to a useful device