Thesis Project Portfolio

Design of a Sensor-Enabled Testing Device for the TrueClot® Tourniquet Application Trainer

(Technical Report)

Ti510(K) Applications and the Risks associated with the Medical Device Regulatory Pathway

(STS Research Paper)

An Undergraduate Thesis

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Sociotechnical Synthesis

In such events like the Boston Marathon, improvised tourniquets were used to stop hemorrhage in fatal wounds. Recent research has shown that the use of a tourniquet is an effective form of hemorrhage control. The main mechanism of a tourniquet is to occlude blood flow in the brachial artery to stop hemorrhage. As more emergency medical services and military personnel began to incorporate tourniquet training into their training, it is crucial that the tourniquet be placed correctly on the wounded individual to stop bleeding. Current methods of training methods can be uncomfortable and unrealistic, increasing the chance for improper tourniquet application. To solve this problem, Luna Labs USA created the TrueClot® Tourniquet Application Trainer as a wearable device that allows for a more realistic tourniquet application scenario and protects the wearer from pinching or pain experienced by the trainer. My technical project is to design a Sensor-Enabled Testing Device for the TrueClot® Tourniquet Application Trainer. The sensor testing system will validate if the occlusion pressures exerted by the tourniquet are similar to occlusion pressures found in literature.

The STS thesis explores 510(k) applications and the risks associated with the medical device regulatory pathway. This thesis aims to bring light to the faulty approval pathway and provides several recommendations for improving the 510(k) application process. The FDA is the main regulatory body of medical devices and highly encourages rapid innovation for the medical device industry. As more medical devices are created and approved each year, it is essential that the medical devices are validated to be as safe and effective as they are marketed to be. The risks associated with a device depend on their device classification, and those that undergo the 510(k) application can have what is classified as a “medium” risk on patients who use the device. Only after consumer advocates and the media exposed adverse events associated with a contraceptive medical device, did the FDA begin to find the balance between encouraging rapid innovation and

consumer safety. After such incidents, both scholars and consumers wanted the FDA to prioritize consumer safety, however leaders in the medical device industry wanted regulations to be less stringent.

In terms of the Capstone project, the group was able to create a functional sensor system that detected occlusion pressures exerted by the tourniquet and found that the sensor system worked differently on different arms. For future research, the sensor system should be able to maintain consistent values on different arms and the trainer could become more portable as opposed to being a stationary testing device. The STS thesis synthesized information from the media, medical device industry experts, and consumer advocates to provide solutions to improving the FDA approval process. Such solutions have been considered by the FDA and the FDA continues to make modifications to important amendments to balance rapid innovation and consumer safety.