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SOL Retractor: Rapidly Deployable Film-Based C-Section Retractor

Casey Lee
Union College - Schenectady, NY

Silas Cleveland
Union College - Schenectady, NY

Jose Dolores Valdivieso
Union College - Schenectady, NY

Joseph Perks
Union College - Schenectady, NY

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Silas Cleveland, Josè Dolores Valdivieso, Casey Lee, Joseph Perks

Advisors: Prof. Shane Cotter, Prof. Sudhir Khetan, Prof. Jennifer Currey

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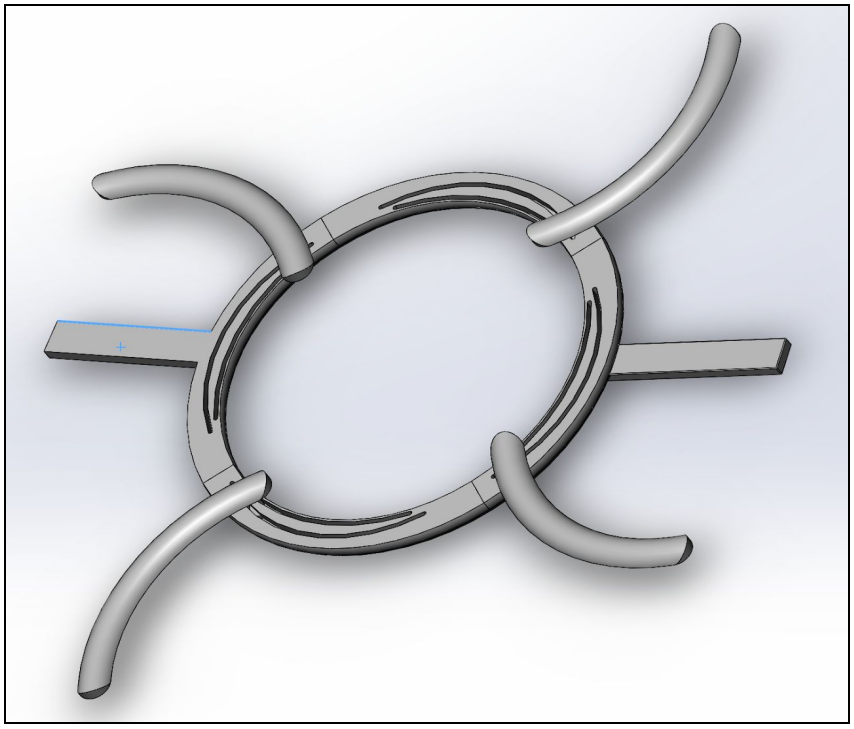

1. Background

1.1 Introduction

A Cesarean section (c-section) is one of the most commonly practiced medical procedures across the United States with an estimated 1,209,000 (31.9% of births) c-sections performed in 2018 [1]. A c-section is a medical delivery of a baby through surgical incisions in both the abdomen and uterus. Depending on the circumstances there are four categories of c-sections:

- Category 1: Life of either mother and/or baby is in imminent danger.
- Category 2: A problem arises that affects the health of the mother and/or baby, but it is not life-threatening.
- Category 3: Baby needs to be delivered early, with no immediate risk.
- Category 4: Planned procedure at a time that works with both the hospital and mother [2].

Procedures that fall under either Category 1 or Category 2 are considered to be emergency c-sections. Category 3 and Category 4 procedures are referred to as scheduled c-sections. While both scheduled and emergency c-sections are comparable invasive procedures, the overall surgical operations are somewhat different and thus can lead to varying amounts of required postoperative care for each procedure.

1.2 Scheduled Cesarean Section

A scheduled c-section is planned for a week prior to the expected date of delivery. Reasons for scheduling a c-section can include health risks that prevent the mother from safely having a vaginal delivery, such as heart problems or HIV, the baby having a birth defect, problems with the placenta, or the mother has already had a previous c-section [3].

1.2.1 Surgical Procedure

Before the procedure begins, either an epidural or general anesthetic is administered depending on the condition of the mother. An incision is made two inches above the pubic hair, also called the bikini cut, that ranges from 9-17 cm based on the size of the baby or the mother [4]. Doctors then retract the abdominal wall and retain the bladder. One of either the two existing surgical retractors, a manual retractor or the Alexis O C-Section Retractor, is inserted into the incision to keep the abdominal wall retained. The retractors can each be seen in Figure 1 below. After the retractor is securely in place, a smaller incision is then made in the uterine wall before the baby is delivered. Depending on either the incisions that were made or the doctor's preference, the uterus may need to be extradited so that the placenta can be removed [5].

Figure 1. The Alexis O C-Section Retractor (left) and a Manual Retractor (right).

1.3 Emergency Cesarean Section

Emergency c-sections are performed when the health or life of the mother and/or baby is at risk. While 32.9% of all births are c-sections, a reported 13% of births were emergency c-sections in 2018 [6]. Some of these situations where an emergency c-section is needed include excessive blood loss during labor, the umbilical cord being wrapped around the baby's neck, the baby being in the wrong orientation, the mother is suffering from preeclampsia, labor not proceeding as normal, or the baby is too large [7]. After doctors have decided to perform an emergency c-section, they must move the mother into the operating room (OR) for the procedure. Since

there is an increased risk to the mother and/or baby, it is recommended by the National Institute of Clinical Excellence (NICE) that there should be no more than 30 minutes from the decision to delivery [8].

1.3.1 Surgical Procedure

After the mother is rushed to the OR, an anesthetic is administered in the same fashion as in a scheduled c-section; however, if the risks are too high, a heavier sedative such as Valium is required. Once the mother is sedated, doctors have only 5 minutes from incision to the extraction and delivery of the newborn [8]. The overall medical procedure is similar to that of a scheduled c-section however, due to the limited amount of time, doctors conduct an emergency procedure with greater haste. This causes doctors to make a few sacrifices to allow for a faster procedure. A smaller and less precise incision and the use of only the clinicians' hands or manual retractors, instead of existing self-retaining retractors designed for c-sections, are a few examples of the sacrifices clinicians make to successfully deliver the baby. These sacrifices lead to a higher risk of excessive blood loss, infection, nausea, and prolonged postoperative care [9]. Due to the high chance of excessive blood loss during the operation, the uterus is typically extradited so the placenta can be removed [10].

1.4 Postoperative Treatment

Mothers typically spend no more than 3 days in the hospital in postoperative care after a c-section, however since the planned procedure is a fairly simple surgery, the majority of mothers leave after 24 hours [6]. During this time, doctors will monitor the mother and baby for any health risks resulting from the procedure. The mother will also be given some form of pain medication to help cope with any postoperative pain. The medicine is usually given through an

intravenous line (IV) [11]. Once the mother is ready, she will be given pain pills that she can administer on her own after she leaves the hospital. It typically takes about a week for the mother to fully recover.

1.5 Existing Cesarean Retractors

Currently, the most popular surgical retractor for c-sections is a manual retractor, as opposed to the Alexis O C-section Retractor, because the latter is considered too expensive for hospitals to use [4]. While manual retractors have a simple design that can be inserted and held in place by a medical student, it does little to minimize postoperative complications compared to the Alexis O Retractor. Another popular self-retaining retractor is the Collins retractor, however, like the manual retractor, this one does little to minimize postoperative complications. A comparative study between the Alexis O Retractor and the Collins Retractor was conducted in 2016 by Hinkson to show the differences between the two retractors [5].

1.5.1 Comparative Study

The study consisted of 200 women who were placed into two groups: n=100 for the Alexis O Retractor and n=100 for the Collins Retractor. The results of the study showed improved results for the Alexis O Retractor group: 35% of mothers in the Alexis O Retractor group required a diathermy, a medical procedure where an electric scalpel is used to cut and cauterize the incision, compared to 82% in the Collins Retractor group, 19% of mothers in the Alexis O Retractor group required extra pain therapy compared to 43% in the Collins Retractor group, 19% of mothers in the Alexis O Retractor group experienced less blood loss (<500ml) compared to 3% in the Collins Retractor group, and 3% of mothers in the Alexis O Retractor group did not require their uterus to be extradited compared to 31% in the Collins Retractor group. A

significant number of doctors from the study ($p < 0.05$) also noted that the Alexis O Retractor provided them with a wider operating area and an easier removal/insertion process [5].

1.5.2 Alexis O C-Section Retractor Cost

The Alexis O C-section Retractor has been shown to be the optimal retractor to use during a c-section through numerous studies [4] [5] [12] [13]. However, in large hospitals like Brigham and Women's Hospital, which conduct up to 3000 c-sections a year, this retractor, running at $75 per retractor, can cost them $225,000 annually [4]. Furthermore, the process of inserting the Alexis O Retractor is simple but takes doctors an excess amount of time that it is unfit for use in an emergency c-section [14]. It is because of these costs that hospitals and health care insurances opt not to use the Alexis O Retractor as a standard medical device.

1.5.3 Current Solutions

There are currently not many commonly used devices or developing patents designed for a self-retaining c-section retractor that can be utilized during an emergency c-section. There are, however, patents for an insertion device for a soft tissue retractor specific to abdominal surgeries [15]. These devices are much smaller in scale and would not fit within a c-section and therefore not applicable as a plausible solution. Several designs are proposed that can reduce the cost of the Alexis O Retractor [16]. These designs are still unsuited for an emergency procedure as the designs follow a similar insertion method to that of Alexis O Retractor, which takes approximately a minute to install [14]. This is too long of a process for validation for an emergency procedure.

1.6 Doctor Cheryl DeSimone

Our group met with our industry mentor, Dr. Cheryl DeSimone, an anesthesiologist who works regularly with Obstetricians and Gynecologists (OG-GYNs) who use the Alexis O Retractor. Some major takeaways from the meeting were that some of the clinicians at Albany Medical Center (AMC) lacked the physical strength to collapse the interior ring or roll the exterior ring to apply the appropriate retraction force for installment. Another issue was that the hands of the clinicians are typically slippery from the surgical gloves and bodily fluids, such as blood, which can hinder the clinician from effectively rolling the exterior ring. Reusable materials such as metal and hard polymers were also discouraged because flexible rings protect the baby and the clinician's hands; AMC was also trying to make the majority of their medical instruments disposable. Finally, we were given an estimate of about 10 seconds for our product to be deployed and implemented for a surgical retractor to be used in an emergency c-section.

2. Problem Statement

Cesarean Sections can be divided into four distinct categories; Category 1 and 2 are emergency c-sections and Category 3 and 4 are scheduled c-sections [2]. A comparative study from 2016 analyzed the difference of need for postoperative treatment between the Collins or the Alexis O C-Section Retractor (n = 100). The Alexis O C-Section Retractor resulted in 19% of women requiring postoperative treatment, including medication, monitoring, and an extended stay at the hospital. Comparatively, an increased level of 43% of the patients required postoperative treatment when the Collins Retractor was used ($p = 0.001$) [5]. The Alexis O C-Section Retractor is the preferred device compared to the Collins Retractor, however, there are some issues that arise with the Alexis O C-Section Retractor. Some clinicians lack the strength to properly deploy

the interior ring or roll the exterior ring to set the Alexis O C-Section in place. Also, the surgical gloves of clinicians become slippery when covered with bodily fluids from the patient, making it difficult for one person to roll the exterior ring. Developing a surgical retractor that is readily available and implemented with ease would drastically improve the patient's health and limit the need for postoperative treatment for a c-section operation. A surgical retractor that accomplishes ease and speed of implementation would allow for the retractor to be used in an emergency situation, where no self-retaining retractor is currently used. **An easier to install and more time-efficient C-section retractor that maintains the benefits of the Alexis O C-Section Retractor would allow more unaided clinicians to use a self-retaining surgical retractor during a C-section operation while also reducing postoperative complications such as blood loss and infection.**

3. Objectives

Before developing our design solutions for c-section retractors, we considered that our device must be self-retaining and safe as our two main objectives. The objective tree that we created for our device can be seen in [Appendix A].

3.1 Objective 1: Self-Retaining

The first main objective was that the surgical retractor should be self-retaining. A surgical retractor can be broadly categorized as either self-retaining or manual. Assistants may hold manual retractors in place for several hours, which leads to muscle fatigue and variability in force application, as well as crowding and impeding around the operating area [18]. Additionally, c-section incisions vary in length, averaging from about 9-17 cm and potentially

require the need for a variety of different retractor types [4]. Therefore, we were looking to design a c-section retractor that would hold its shape autonomously for a variety of incisions to fulfill the self-retaining objective and thus allow for an efficient surgical procedure as surgeons can solely focus on the procedure rather than on the instrumentation.

3.2 Objective 2: Safe

The other main objective we determined as a priority is for our device to be safe to use. Like most other medical devices that are in contact with the body, there is a need for our device to be biocompatible to limit complications such as coagulation, blood loss, and infection while the retractor was in contact with an open incision. Our device should also include the benefits of our reference device, the Alexis O Retractor, by limiting postoperative complications including tearing from tension damage. Finally, to set apart our device from other current solutions, we wanted our device to be much easier to use. We wanted our device to be intuitive, fit in the hand of a single user and only take one person to install the device, be quick to implement into an incision so that our device can ultimately be used in emergency c-sections, and improve the visibility and operating area for a safe and smooth delivery. Altogether, our device seeks to either maintain or improve upon the safety benefits compared to other self-retaining c-section retractors, such as the Alexis O C-Section Retractor.

4. Device Functions and Specifications

Our device focuses on improving the safety of c-sections by reducing complications during and after the procedure. Current design solutions, such as the Alexis O Retractor, have limits in insertion time and difficulty to install, as it takes an extensive amount of time to implement and

is difficult for physicians to install due to their own strength or wet surgical gloves causing the device to slip out of their hands. Our device must be inserted into the incision as soon as the initial incisions are conducted, where it can ideally be left unattended and not cause a hindrance to the doctor during the procedure. As it is placed and inserted, the retractor must allow for maximum visibility throughout the delivery of the newborn. In other words, retraction and exposure must be fulfilled for the design to meet its basic standards, which can be seen below in Table 1.

After meeting with Dr. DeSimone, we reevaluated the design and function specifications that we had set for our device, as seen in Table 1. We changed the c-section categories because we wanted our device to be used from the original goal of all four categories to just Category 3 and 4. Next, we updated the ideal amount of time necessary to install our retractor from 20 seconds to 10 seconds; 20 seconds was also reassigned as the marginal value. We also added a new specification pertaining to the number of hands necessary to install the device. The marginal value is two hands used by one person, but one hand would be ideal.

Specification	Metric	Unit	Marginal Value	Ideal Value
Type of C-section	Category	1,2,3,4	3,4	1,2,3,4
Retraction Force	Force	Newtons	125	250
Number of Hands	Number	Number of Hands	2	1
Time to Install/Retract	Time	Seconds	20	10

Table 1. Specification values for functions.

5. Documentation of the Proposed Design

The approach for our design solution was based on the Alexis O C-Section Retractor to maintain the same improvements over the Collins and most other self-retaining retractors. Our designs focused on decreasing the time of implementation, as well as making the retractor easier to use by decreasing the number of operators required. In order to achieve these objectives our design used expanding fins on the exterior ring to apply tension and retract the film, as opposed to the Alexis O C-Section Retractor which wrapped the retracting film around the exterior ring.

5.1 Expanding Fin Mechanism

The expanding fins of the exterior ring, seen below in Figure 2, would begin in line with the exterior ring and attached to the film at the non-rotating end. Once deployed, the fins would retract the film by approximately 1.5 times the radius of the exterior ring, producing an even tension as the radial distance increased. The fins are controlled by a cam system working between the two sections of the exterior ring. When these two sections are rotated in opposite directions the channels of the cam system move with them, and the overlap between the two channels progresses from one end of the track to the other. The fins are connected to these channels by two pins. One pin is stationary in relation to the bottom track and provides the pivot for the rotation of the fin. The other is free to move and is inserted in the overlap between the two channels. The bottom channel provides the guide and is a 135 degree semicircle centered around the pivot pin, which allows the fin to start closed and open up to maximum retraction. The channel of the middle section is a 135 degree arc spread across 60 degrees of the exterior

ring and guides the pin around the guide channel. Using handles attached to the bottom and middle sections of the exterior ring, the clinician would rotate the two sections in opposite directions, forcing the change in channel alignment and extending the fins to apply tension to the film of the retractor.

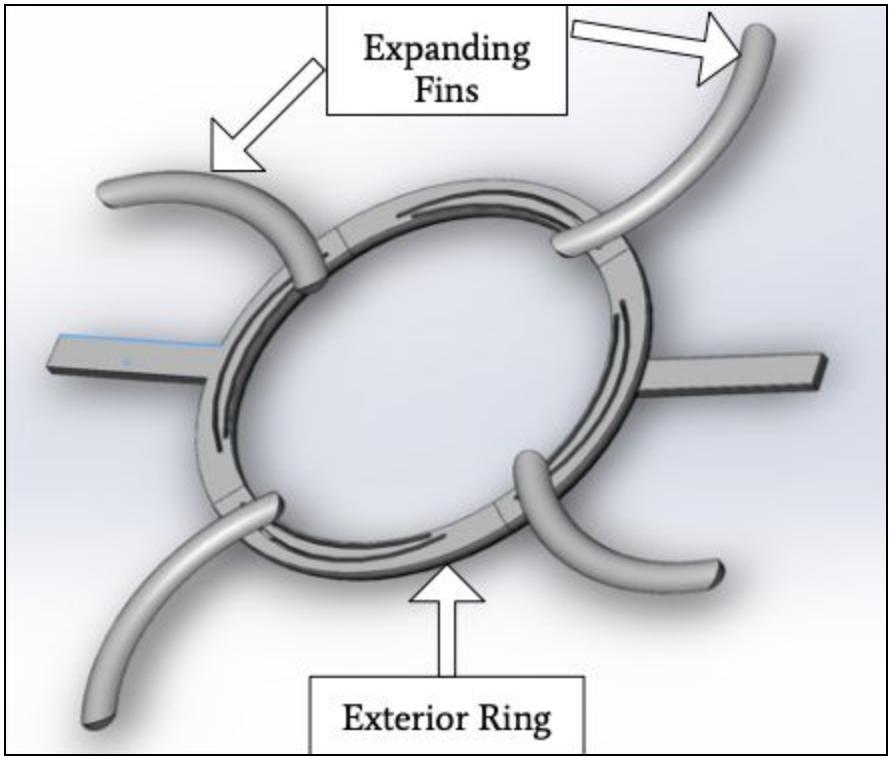

Figure 2. Exterior Ring design with Expanded Fins

5.2 Modification of Retracting Sleeve

In order for the film of the retractor to withstand the radial expansion of our exterior ring design without tearing, it was necessary to redesign the film and modify the original cylindrical shape. While the interior ring and therefore the interior edge of the film would stay the same size, the exterior ring would increase its radius significantly, which would stretch and tear the top edge of the film. However, by using the extended radius as a baseline, the conical-shaped film would be able to handle the radial change, folding back into a cylinder when the fins were retracted. This

conical shape was designed using the measurements for the expanded exterior ring in combination with the measurements of the base Alexis O C-Section Retractor film. An image of the conical-shape film design can be seen below in Figure 3.

Figure 3. An image of the conical shape film design. The top of the image is where the interior ring would be located and the bottom of the image is where the expanding exterior ring would be located

6. Validation of Design

One of the design specifications that we set for our device was the retraction force. Ideally, we wanted our device to produce an ideal maximum of at least 250 Newtons, but marginally a maximum of 125 Newtons. The human body also varies in size and can exert a diverse amount of force on the surgical retractor. We developed a way to test that our device can support various levels of inward radial force. Our testing apparatus included a workout band, two pins, and a piece of wood. We drilled holes into several places along the wooden board. One of the pins was screwed and locked in place. The other pin can move from hole-to-hole and vary the distance between the two pins. The workout band is placed around each of the pins. The varying distances between the two pins created a greater tension in the workout band, creating variable levels of inward radial force. The design for our testing apparatus can be seen below in Figure 4. We also

tested the capabilities of the workout band by use of an INSTRON machine. We stretched the workout band 213.38 mm that produced a load of 98.35 Newtons. Although this force did not reach our marginal maximum retraction force, this value provided us enough force to give us insight on our device.

Figure 4. An image of the testing apparatus that produces variable levels of inward radial force.

We first inserted the Alexis O Retractor into our testing apparatus to ensure that our apparatus functioned properly, which can be seen below in Figure 5. We then put several iterations of our design into the testing apparatus for comparison. We determined that some of our devices would take too long to implement and required an excessive amount of force compared to the Alexis O Retractor. However, our recent prototype made mostly of wooden material and a plastic bag was able to produce the desired support to retract the inward radial force, which can be seen below in Figure 6. Also, it was faster and easier to implement our device than it was the Alexis O Retractor which is an encouraging sign and provides validity to our design.

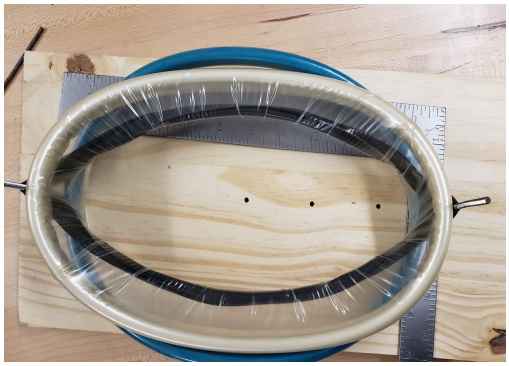

Figure 5. An image of the Alexis O Retractor in the testing apparatus.

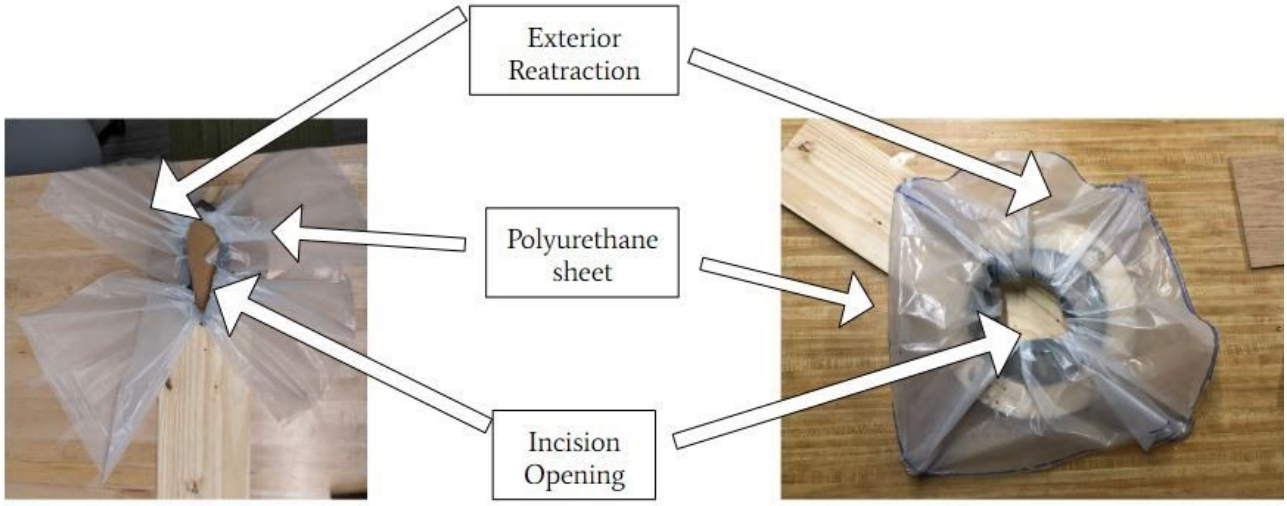

Figure 6. Images of two of our design prototypes. On the left is an image of the single ring design and on the right is an image of the prototype with the expanding ring design both in the testing apparatus.

7. FDA Review Process

Under the Department of Health and Human Services, the Food and Drug Administration (FDA) in part focuses on reviewing medical devices used and sold in the United States. More specifically, the Center for Devices and Radiological Health (CDRH), funded by Congress and through user fees, regulates medical devices ranging from surgical instruments to electronic

and diagnostic equipment. The Sol Retractor is a surgical instrument that fits within the purpose indoctrinated by the FDA intended "for use in the cure, mitigation, treatment, or prevention of disease in man…" [18]. Considering that the Sol retractor would primarily be used in scheduled c-sections, the level of risk would be moderate despite its invasive nature. Therefore, this C-section surgical retractor would be classified under a Class 2 Device and eligible for a 510(K) or Premarket Notification (PMN) considering previous surgical retractors have been approved.

The PretzelFlex Surgical Retractor, whose 510(K) number is K123110 is a device classified as a Laparoscope, normally used in General and Plastic surgery and specializes in gastroenterology and urology, a field where other variations of the Alexis O C-Section Retractor is utilized. The applicant, Surgical Innovations PLC residing in Leeds, West Yorkshire and founded in 1992 produces innovative Laparoscopic instruments that are applied in minimal invasive surgery. The classification product code of the PretzelFlex Surgical Retractor belongs to GCJ, where regulation description pertains to endoscope and accessories as its review panel consisted of General and Plastic Surgery. The regulation number of this surgical instrument is 876.1500, whereas April 1st, 2019, belongs to Gastroenterology-Urology devices as a diagnostic tool. Furthermore, in the Code of Federal Regulations, this device is identified for its use to "provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals" [19]. The classification of this device pertains as a Class 2 due to endoscopic procedure that is exempt from premarket notification.

In an address directed towards Tracey Fearnley, a representative of Surgical Innovations, the FDA approved the Pretzelflex Surgical retractor as substantially equivalent to previous traditional surgical retractors submitted in years prior. The indication of use for this device is designed as an organ and tissue retractor used in invasive surgical procedures to allow improved access and visualization of the surgical site [20]. Concluding that this surgical retractor is cleared from Pre-Market Approval, the FDA stresses that Surgical Innovations must follow the guidelines and regulations with strict controls on their device, which if altered, will no longer be cleared for approval.

Although the Sol Retractor's intended use is comparable to the PretzelFlex Surgical Retractor, where its intended use is for a clearer operational site and exposure, it is significantly more invasive considering the nature of newborn delivery in C-sections. Due to this, the classification and regulations of previous FDA approved surgical instruments will not be comparable when classifying our retractor. This would mean that the PMA or the 510(K) notification will no longer apply to our retractor despite its inherent similarities. In other words, the regulations that the FDA underlined in their approval address towards Surgical Innovations, where changes in the classification of our device will be subject to additional controls affecting its review of premarket notification.

As our team furthers our surgical instrument to accomplish our indication of use in efficiency and improvement from the Alexis O retractor, we hope to obtain FDA approval for scheduled C-sections with future plans to eventually address the shortcomings that prevent instrumentation use in emergency C-sections. Thus, through a surgical retractor that provides clear exposure and ease of use on the operational area, we present to you, the Sol Retractor.

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Appendix A. Objectives Tree