

10. Summary Report.

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510 (k) Summary

SURCRAFT, LC is claiming equivalence of the McGivney hemorrhoid ligator and the Hirschman anoscope and Brinkerhof rectal speculum.

The new device is therefor a socalled "combination" devise that claims to have the same intended uses as several different types of predicate devices

The new device has incorporated features of the above tools into one device, resulting in one instrument that can bring into view and ligate hemorrhoids, all at the same time, by the operating surgeon. No assistant is needed. The tool is a double barreled tube, the internal tube carrying a preloaded latex elastic band slightly protuding from the external tube. An obturator is inserted into the devise and after adequate lubrication, the tool is inserted into the anal canal and rectum. The obturator is then removed. The anatomical site for banding is chosen, by acurate positioning the tool. A long narrow, angled tenaculum, or any other grasping device is inserted into the tube, the chosen tissue is grasped and pulled into the tube. The inner tube is retracted with the operators thumb and the outer barrel pushes the elastic band off the internal barrel and the band lodges around the tissue.

The solo Band Ligator is simpler than the predicate devise and because of its design is easier to clean without hard to get to parts. There are no small openings that can clog up with debris, no springs, no adjustment screws.

Both tools accomplish the banding procedure well, but the Solo Band Ligator does it more accurately and under full manual and visual control of the operating surgeon. He does not have to depend on the assistant (who cannot see what he is doing) holding the tool at the critical moment when the instrument has to be fired. The Solo Band Ligator has been succesfully used in approximately 100 hemorrhoid ligations on an outpatient basis in my office, .over the past two years. Other than greater ease of the procedure for the surgeon, no significant differences before, during or after the banding procedure, were observed by the surgeon or the patient.

In view of all of the above I conclude that the Solo Band Ligator in its current configuration is functionally essentially equivalent to the predicate devise (Hemorrhoid Ligator) and structurely and functionally equivalent to the Anoscope and Rectal Speculum (Hirschman and Brinkerhof). Clinical results of the rubber band procedure with one or the other tool are identical. The new devise is easier to clean, provides a better view and is under solo operated control by the surgeon.