**Liver Retractor Swine Study**

**Sponsor:** Boehringer Laboratories, LLC.

**GLPs Required?** Yes

**Purpose:** This document summarizes requirements provided by Boehringer Laboratories, LLC. (BL) for the purpose of obtaining quotes for a comparative animal study in support of a 510(k) Medical Device Submission.

Subjects needed

* 80-100kg swine
* N = 3
* Exclusion criteria:
  + Animals determined to be unhealthy prior to start of study
  + Animals with noted liver abnormalities upon surgical entry

Duration

* 180-minute device use
* 5-day post-op sacrifice

Devices (provided by BL)

* 3 BL Organ Retractors (subject device)
* 3 LiVac Liver Retractors (FDA cleared predicate/comparator device)

Equipment required

* Operating room
* Laparoscopic tower
  + 0° or 30° laparoscope, scope console, light source, screen/monitor
  + Insufflator, insufflator tubing
* Suction source (> 500mmHg)
* Laparoscopic tooling
  + 12 mm & 5 mm trocars
  + Laparoscopic graspers (e.g., Maryland)
  + Suture passer (i.e., Carter Thomason)
  + Scissors
* Suction tubing
* Force gauge (max 10 lbs)

Device Placement Method and Location

* Both devices are to be operated in accordance with device instructions for use (IFU)
* LiVac placement location:
  + One side of device attached to the ventral side of right lobe, one side attached to neighboring peritoneum
  + Pressure setpoint: 500 mmHg
* BL Retractor placement location:
  + Dorsal/underside of left lobe with applied pull force of ≥ 2.5 lbs
  + Pressure setpoint: self-regulated, suction source required
* Either or both placements may change following practice (cadaver) study
* Measure where devices were placed relative to anatomical landmarks immediately after placement so they may be properly identified at 5-day follow-up

Outputs

* Imaging
  + Gross anatomical analysis via laparoscopic photos taken @ t=0, t=180 min, t= 5 days
  + Camera must remain in place for full 180-minute use duration to maintain constant visual of devices
  + Gross observations should be performed by same observer at all time points
  + Numerical scale must be used for gross tissue analysis and comparison
* Histology
  + Cellular analysis performed at 5-day time point following animal sacrifice
  + Cell imaging required to support analysis, must be included in final report
  + Numerical scale used to determine level of cell disruption and for comparison between devices

Misc.

* If either device releases the liver, the drop is to be noted, and the retractor replaced in the same position with the same method as initial setup. Time will pause at the drop and resume after replacement of device. The total contact time for each device must be 180 minutes.
* Non-NSAID painkillers post-op