An Acute GLP Safety Evaluation of the Vein Device on the Swine Model

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The purpose of this study was to confirm that the Vein Device (now known as Veinplicity®) did not induce any clinically relevant changes in clinical pathology.

The primary study endpoint was a pathologic change in laboratory parameters (clinical pathology) defined as the change of the complete blood count (CBC) and of serum chemistry at predetermined time points.

The animal study was a control study with two subjects. One animal received maximum stimulation for 10 minutes with the device and the other received no treatment and served as a control. Blood for clinical pathology was collected and analysed at baseline; 5, 10, 15, 30, 60, 90 and 120 minutes post treatment initiation.

No changes in blood chemistry between the control and treatment animal were observed. The tests undertaken were: CBC (RBC, Hb, Hemacrit, Platelet Count, WBCC, 5 part WBCD), Serum Chemistry (Urea Nitrogen, Creatinine, Total Protein, Albumin, AST, Bicarbonate, Glucose, Sodium, Potassium, Chloride, Calcium and Phosphorus), LDH and Lactic Acid.

The study successfully met all endpoints and no relevant changes to the blood chemistry were observed within the animal model.