

Michael A Daniel – CV

BS Microbiology – Michigan State University

MS Biology – Illinois Institute of Technology

MBA – University of California, Berkeley

1982 – 1992 – Various quality/regulatory/project management positions with first **Novacor Medical Corp.** and then **Novacor Division of Baxter Healthcare** (Implantable Left Ventricular Assist Systems)

1992 – 1994 – Director, Regulatory/Quality for **Smith Kline Diagnostics** a division of Beckman Instruments (*In vitro* Diagnostics)

1994 – 1996 – Vice President, Regulatory/Quality for **FemRx** (Endometrial Resection and Ablation and fluid management medical devices). IPO in 1996.

1996 – 1999 – Vice President, Regulatory/Clinical Affairs for **Intuitive Surgical** (Robotic endoscopic surgical devices). IPO in 1999.

2007 – Pres. – Vice President, Regulatory/Clinical Affairs for **EndoGastric Solutions** (Transoral surgical devices for GERD and Bariatric revision)

1985 – Pres. – **Daniel & Daniel Consulting** – providing regulatory and clinical affairs consulting for medical device companies often as “Acting VP”. (See partial list below)

FDA IDE / 510(k) / Canadian / European CE Mark Approvals for which I was responsible:

SKD – Immunochemical IVDs – Clinical study and 510(k) clearance for H. pylori (ulcer) test.

FemRx – Clinical study and 510(k) clearances for endometrial ablation and fluid management systems

Intuitive Surgical – IDE clinical study, FDA Panel meeting approval, 510(k) clearances and CE marks for surgical robotics systems

Coalescent Surgical – IDE clinical study, 510(k) clearances and CE mark for coronary anastomotic clips

LuMend – IDE clinical study, 510(k) clearances and CE marks for percutaneous coronary catheters

Kerberos – 510(k) clearances for percutaneous peripheral and coronary catheters

Emphasys – Contributed to early clinical study design for endobronchial valves (510(k) was found NSE)

NeoGuide – OUS clinical study and 510(k) clearance for semi-automated colonoscope system

DyAnsys – 510(k) clearance for ECG diagnostic system

BridgePoint Medical – IDE study initiation and 510(k) clearances for coronary catheters and guidewires

EndoGastric Solutions – IDE clinical study and 510(k) clearances for transoral surgical devices, GERD indication and IDE unconditional approved for post bariatric study

Recent/Current Projects:

Vascular access closure device clinical study underway

Left Atrial Appendage occlusion device, IDE clinical study unconditionally approved and underway