

Daniel & Daniel Consulting

Regulatory and Clinical Affairs Consulting for Medical Device Companies

June, 2009

Dear Investor / Board Member / Entrepreneur,

Daniel & Daniel Consulting has been helping small to medium size medical device companies develop clinical and regulatory strategy, complete clinical studies and gain FDA product clearance/approval since 1985. Over this time we have successfully designed and completed over a dozen clinical studies (6 IDEs), and obtained FDA clearance or approval for over 50 devices.

Our expertise includes:

- 1) Clinical study strategy, design and negotiation with FDA
- 2) IDE submissions, negotiations, and approvals
- 3) Clinical study management to successful completion
- 4) 510(k) or PMA strategy, submissions, negotiations and clearance / approval
- 5) Post market and investigator initiated studies
- 6) Regulatory compliance and quality systems

We have extensive experience in the following areas of clinical medicine:

- 1) Cardiovascular
- 2) Cardiac surgery
- 3) Interventional Cardiology
- 4) Gastroenterology
- 5) General Surgery and Bariatrics
- 6) Electrocardiography

We have worked repeatedly in the following technology areas:

- 1) Endoluminal and transoral devices
- 2) Percutaneous, peripheral and coronary catheters
- 3) Robotics
- 4) Ablation
- 5) Implantable circulatory support systems
- 6) *In vitro* diagnostics (IVDs)

Please reference the attached founders CV for additional details. We would welcome the opportunity to assist you or any of your portfolio companies.

Sincerely,



Michael A. Daniel
President, and Founder
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<http://www.clinregconsult.com>