

Team Medical, LLC Capabilities Statement

30 years Medical Device R&D – Over 100 products designed and evaluated

Team Medical Capabilities

Product Design

- Design and Engineering
- Analysis and modeling
- Concept evaluation and test
- Proof of principle model creation and test
- Product architecture and system design
- Prototype fabrication
- Design review
- Project review

Verification & Validation and Product Test

- *In vitro* in our laboratories
- *In vivo* with established outside laboratories
- Test protocols and test fixtures
- Manage biocompatibility tests

Product Evaluation

- Feasibility assessment
- Risk analysis: Hazard Analysis, Fault Tree Analysis, FMEA
- Reliability assessment
- Feasibility to design around patents

Patent Litigation Support

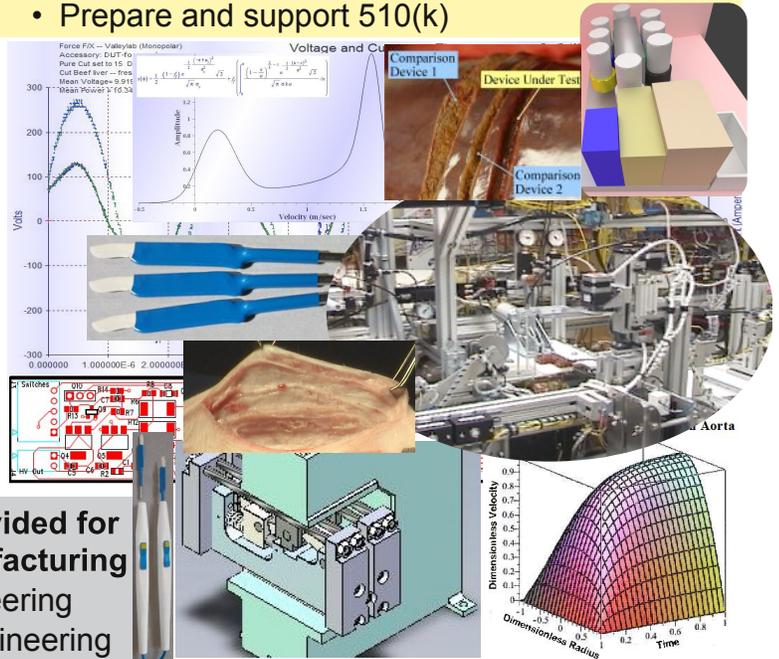
- Validity analysis
- Infringement analysis

Engineering Provided for Products & Manufacturing

- Systems Engineering
- Mechanical Engineering
- Electronic Engineering
- Software Engineering
- Useability Engineering
- Manufacturing Engineering

Our analyses and documents get to the core issues

- Evaluate technical feasibility
- Produce designs that meet requirements
- Risk analysis and control
- Test to determine compliance with requirements
- Review and Audit Projects and Designs
- Prepare and support 510(k)



Experience includes:

- Diagnostic and therapeutic products
- Drug delivery systems
- Catheters and endoscopes
- MIS, arthroscopic, and open surgical instruments
- Cardiac function and output
- Energy based (electrosurgical/RF) and mechanical surgical instruments
- Blood glucose monitors
- Mechanical, electronic, and software systems
- Hospital & alternate care site products

Over 25 U.S. Patents with others pending
Registered Professional Engineer
Dartmouth College A.B, B.E., M.E. (1973, 1974, 1975)

When you need a real hands-on expert on medical device technology and development give me a call.

I'm here to help you.

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Summary

Mr. Heim started providing consulting services in 1976 in Washington, D.C. where his clients included The White House, federal agencies, and private clients for whom he evaluated new energy technologies. He now develops and evaluates sophisticated multi-disciplinary medical devices, activities that started over 30 years ago. Over 25 U.S. medical device patents list him as an inventor in the fields of electrosurgery, drug delivery, and cardiology. He evaluates product technologies and product concepts, invents and develops products, assesses their intellectual property, and brings them into production. Mr. Heim has worked with most of the large U.S. medical device companies as well as startups. He provides system design, mechanical and electronic engineering, and develops controlling and sensing algorithms.

Experience includes mechanical engineering, electronic and control engineering, software engineering, chemistry, thermodynamics, heat transfer, materials science, and experimental design and analysis. Have had excellent working relationships with mechanical, electronic and software engineers, designers, and technicians, machine shops, vendors, industrial and human interface designers, and independent laboratories that conduct animal studies and conduct histology evaluations. Mr. Heim has worked with clinical advisor physician experts for over 20 years.

Professional Career

Team Medical, LLC 1996 - Present –
Founder and CEO
Boulder, Colorado

Team Medical conducts research and development of advanced medical devices.

Surginetics LLC 2006 - 2007 –
Executive Vice President and
Chief Technical Officer
Boulder, Colorado

Surginetics was created to commercialize a set of technologies developed and patented by Team Medical, LLC. Surginetics sold its IP portfolio to a subsidiary of a multibillion dollar company.

Over 100 medical device projects have been done including developing or supporting development of:

- Surgical instruments
 - orthopaedic instruments, including RF ablation, cutting, and tissue shrinkage
 - monopolar and bipolar electrosurgical instruments and generators
 - minimally invasive surgical instruments
 - endoscopes – cardiac, vascular, urologic
- Cardiac and vascular care and monitoring
 - intracardiac catheters
 - multiparameter hemodynamic monitor
 - left ventricular assist device (LVAD)
- Patient monitoring and treatment
 - noninvasive blood glucose meters
 - pulse oximeters
 - spirometers
 - implantable bioartificial pancreas
- Drug delivery systems
 - hospital infusion pumps
 - ambulatory infusion pumps
 - miniature infusion pumps

Consulting services provided to many firms, including Abbott Laboratories, Baxter, C.R. Bard, Edwards Life Sciences, Linvatec (division of Conmed), Medtronic, St. Jude Medical, Johnson & Johnson, Smith+Nephew, Valleylab (Covidien).

The Larren Corporation 1988 - 1996 – Founder and President
Boulder, Colorado

The Larren Corporation became one of the United States' premier contract medical device product research and development companies. Larren provided the full range of electronic, mechanical, software, manufacturing, and quality assurance engineering needed to bring products from conception to production. Larren was successfully sold to Battelle and Mr. Heim continued developing medical devices with Team Medical, above.

Rela, Inc. 1987 - 1988 – Group Director
Boulder, Colorado

Mr. Heim set up and managed the medical device product development group at Rela, a multi-disciplinary contract product development company.

Valleylab, Inc. (a unit of Pfizer, now Covidien) 1982 - 1987 – Engineering Manager
Boulder, Colorado

As an engineer and Engineering Manager at Valleylab, Mr. Heim worked in the Infusion Systems Division, which designed, manufactured, sold, and serviced precision medication delivery pumps and the disposables that they used. Mr. Heim managed Valleylab's largest engineering team and developed new products and improved the reliability and profitability of existing products.

Energy and Resource Consultants 1979 - 1982 – Founder and Principal
Boulder, Colorado

Energy and Resource Consultants provided technical and economic consulting services to private and public sector clients in fields including biomass fuels, small scale hydroelectric, synthetic fuels, renewable energy, and electricity use forecasting.

Energy and Environmental Analysis, Inc. 1976 - 1979 – Project Director
Arlington, Virginia

Mr. Heim provided technical and economic consulting services to private and public sector clients including the Executive Office of the President of the United States with expertise on alternative fuels, fuels combustion, green energy, and energy demand forecasting.

Gulf Oil Company 1975 - 1976 – Project Engineer
Dupont, Washington

Mr. Heim was one of the engineers selected to lead Gulf Oil's (purchased by Chevron) move into alternative fuels. He improved and developed processes and equipment at a plant designed to convert coal into clean burning fuels.

Dartmouth College, Thayer School of Engineering 1973 - 1975
Hanover, New Hampshire

The National Science Foundation funded Mr. Heim's graduate studies examining heat transfer and energy conservation in residential buildings.

Registered Professional Engineer, State of Colorado

Education

1975 – Master of Engineering, Dartmouth College, Thayer School of Engineering
1974 – Bachelor of Engineering, Dartmouth College, Thayer School of Engineering
1973 – A.B. (Bachelor of Arts), Dartmouth College