Who are These Folks?

As we do at the beginning of each new year, we took a look back at 2007 and the companies that received their first 510(k) clearances through the FDA orthopaedic panel. What an interesting group.

We profile these companies below with information available in the public domain.

**BENVENUE MEDICAL**
Mountain View, California USA
www.benvenuemedical.com
➢ Benvenue VCF Osteo Coil System
   • K070293
   • Features Nitinol Osteo Coil, deployment cannula with PEEK liner and handle
   • Indicated for the treatment of pathological vertebral compression fractures... by creating channels in the existing spinal bone structure for the flow of bone cement
➢ Recently closed $15MM in financing; funds to be used to expand product development, obtain additional regulatory approvals and gain clinical experience
➢ Also developing technology with application in treatment of degenerative disc disease

**BIODUCT LLC**
Fort Wayne, Indiana USA
www.schwartzbiomedical.com
➢ BioDuct
   • K053492
   • Bio-absorbable meniscal fixation device
   • Intended for fixation of longitudinal vertical meniscus (bucket handle) lesions located in the vascularized (red-white) zone of the meniscus when used with suture
➢ Also developing partial resurfacing implant and joint bearing technologies derived from UHMWPes and a naturally occurring polysaccharide molecule and soft tissue fixation technologies as well as tissue engineering scaffold technologies derived from hyaluronic acid

**C2M MEDICAL, INC.**
San Antonio, Texas USA
➢ Cinch Knotless Fixation Implant
   • K073226
   • 3.5mm diameter anchor preloaded with inserters
   • Modification to the original Cinch Bone Anchor System K062739 granted to Sapphire Medical in 2007 (WRC Anchor with curved PEEK base, flared nitinol clip, two nitinol laser cut rings and nitinol anchor pin; and RRC Anchor with machine molded cylindrical PEEK base, two nitinol laser cut rings and nitinol anchor pin)
   • Intended to be used for fixation of soft tissue to bone during rotator cuff repair
➢ “Captive consulting group providing ‘Concept to Market’ advisory services to portfolio companies”

**CALCITEC, INC.**
Austin, Texas USA
➢ OsteofiX Bone Void Filler
   • K070220
   • Resorbable, injectable filler composed primarily of calcium phosphate, sodium phosphate, deionized water and calcium oxide
   • Indicated for use to fill bony voids or gaps... (that are not intrinsic to the stability of the bony structure)
➢ Also created CortiCell a resorbable, injectable, synthetic structural bone graft
➢ Numerous U.S. patents

**CORE ESSENCE ORTHOPAEDICS, LLC**
Yardley, Pennsylvania USA
www.ceortho.com
➢ reNOVOTM Suture Anchor System
   • K071520
   • Suture Anchors available in 2.0mm to 5.5mm diameters, preloaded with ultra high molecular
Newcomers...

(Continued from page 1)

weight polyethylene (UHMWPE) sutures

Available in traditional (with needles) and
arthroscopic (without needles) configurations

Intended to secure soft tissue to bone in
shoulder, elbow, hand/wrist and foot/ankle
applications

➢ reVERTOTO Shape Memory Staple System
   • K071477
   • Dynamic compression implants using shape
     memory metal nickel-titanium (NiTinol) alloy
   • Indicated for use in fixation of osteotomies of
     the hand, foot and tibia; fusion of hand and
     foot joints; soft tissue to bone fixation and in
     adjunctive fixation of small bone fragments of
     upper and lower extremities and upper torso
   • Patent pending heat activation system and
     method

➢ Currently launching reNOVO and reVERTO
   along with the SEG-WAY™ Endoscopic Liga-
   ment Release System

➢ Developing the SECURUST™ patent pending
   system for knotless suture anchor repair

➢ Developing PONTIS™ patented and patent
   pending system for minimally invasive endoten-
   donous repair of severed or grafted tendons
   about the extremities

ELITE SURGICAL SUPPLIES PTY.
Pretoria, South Africa
www.elitesurgical.com

➢ Vertefix Pedicle Screw Spinal System
   • K063453
   • Ti alloy posterior fixation system with pedicle
     screws, rods, set screws, connectors, hooks
     and transverse (cross) linking mechanism
   • Intended for posterior, non cervical pedicle
     fixation

➢ Also markets hip, knee and shoulder implants,
   fracture repair products and spine cages

FXDEVICEs
Boca Raton, Florida USA
www.fxdevices.com

➢ Lagwire
   • K070393
   • 4.5mm Ti alloy wire in various lengths + cap
   • Intended for use in the general management
     of fractures and reconstructive surgery

➢ U.S. patent application 20070162026, “System
   and Method for a Cap Used in the Fixation of
   Bone Fractures”

GOLD STANDARD ORTHOPAEDICS, LLC
Louisville, Kentucky USA

➢ GSO Bone Fixation Fasteners
   • K063589
   • Sterile and non-sterile 316-LVM stainless steel
     smooth and threaded K-wires, Steinmann
     pins and malleolar bone screws
   • Indicated for use in fixation of bone fractures,
     for bone reconstructions, as guide pins for
     insertion of other implants or implantation
     through the skin

IMPLANTS INTERNATIONAL
Thornaby-On-Tees United Kingdom
www.implantsinternational.com

➢ Cermet III Acetabular Cup System
   • K071583
   • Non-cemented Ti alloy acetabular cup system
     with assortment of neutral and 10° hooded
     poly inserts + screws and screw hole covers

➢ Rigi-Fix Hip Stem System
   • K072101
   • Ti alloy proximally coated hip stem with com-
     mercially pure Ti plasma spray

➢ Also sells a variety of implants for joint replace-
   ment (hip, knee, shoulder, wrist, elbow), fracture
   repair (compression hip screw, IM nail, screws)
   and spinal fusion (cages, pedicle screw and plate
   systems, dynamic cervical plates)

➢ Developing metal-on-metal (MoM) hip resurfac-
   ing, PEEK cages, MoM disc spacer, bone ce-
   ments and bone graft substitutes

INTRINSIC THERAPEUTICS
Wilmington, Massachusetts USA
www.in-or.com

➢ Fixation Staple
   • K071637
   • Ti alloy
   • Intended for providing soft tissue fixation to
     bone in procedures such as tendon repairs,
     transfers or transplants; ligament repairs, re-
     construction or replacement in which the
     ligament is fixed to the bone

➢ Also developing annular repair device

➢ Issued numerous U.S. patents for nucleus
   pulposus augmentation and retention, annulus
   fibrosis reinforcement, disc manipulation and
   augmentation and disc prosthesis design and
   methods of manufacture

(Continued from page 1)
Newcomers...

(Continued from page 2)

ISTO TECHNOLOGIES, INC.
St. Louis, Missouri USA
www.istotech.com

➢ InQu
  ✓ K063359
  ✓ Resorbable, granular bone void filler device composed of poly (D, L lactide-co-glycolide) and hyaluronic acid
  ✓ Available in 10cc and 30cc quantities
  ✓ Indicated for use to fill bony voids or gaps…
  ➢ Also developing:
    ✓ NuQu patent pending injectable cell therapy (culture-expanded juvenile cartilage cells in a protein-based carrier) for treatment of underlying cause of back pain
    ✓ DeNovo ET scaffold-free living cartilage implant designed as an off-the-shelf product to repair and regenerate damaged knee cartilage; currently in Phase I/II clinical trials; in collaboration with Zimmer

JEMO SPINE, LLC
Murray, Utah. 84107
www.jemospine.com

➢ Delta Spinal Fusion System
  ✓ K071857
  ✓ Ti alloy top-loading posterior spinal fixation system with pedicle screws, rods, cap/set screws, transverse (cross) linking mechanism
  ➢ Also developing interspinous process dynamic stabilization, anterior cervical plate, interlaminal fixation, flexible rod, interbody spacer systems

JG MEDICAL PRODUCTS LLC
Huntington, New York USA

➢ Italite Light Wand Arthroscope
  ✓ K070021
  ✓ Semi rigid, one-channel wand (illumination only), with illumination perpendicular to shaft
  ✓ Intended for illumination during joint examinations, biopsies and in minimally invasive joint procedures
  ✓ Not intended for viewing

MEDICAL BIOMAT
Vaulx-en-Velin, France
www.medicalgroup.fr/MedicalBiomat.html

➢ Atlantik Bone Void Filler
  ✓ K070794
  ✓ Microporous and macroporous biphasic calcium phosphate ceramic consisting of 70% hydroxyapatite (HA) and 30% beta-tricalcium phosphate (TCP); available in granules and blocks
  ✓ Indicated for use to fill bony voids or gaps…
  ✓ Also available with gentamicin ex-U.S.
  ➢ Coating, packaging and testing services through “sister” companies

MEMOMETAL TECHNOLOGIES
Bruz France
www.memometal.com

➢ Bone Anchors
  ✓ K071941
  ✓ Shape memory nickel titanium alloy
  ✓ Indicated for use in hand ligament reconstruction, ankle midfoot reconstruction, hallux valgus reconstruction and scapholunate ligament reconstruction

➢ Varisation Staples
  ✓ K070033
  ✓ Wrought stainless steel staples intended to be implanted for fixation of small bone fractures or for small bone reconstruction; indicated for Akin type osteotomy

➢ Memory Staples
  ✓ K070031
  ✓ Shape memory metal bipodal or quadrupodal compression staples
  ✓ Indicated for hand and foot bone fragments, osteotomy fixation and joint arthrodesis

➢ Fixos Screws
  ✓ K070039
  ✓ Ti alloy cannulated compression and snap-off screws
  ✓ Indicated for fixing and stabilizing elective osteotomies of mid-foot bones and metatarsal and phalanges of the foot only

➢ Intra-medullary Bone Fastener
  ✓ K070598
  ✓ Shape memory alloy “Double X-shape K-Wire”
  ✓ Indicated for small bone reconstruction limited to inter-digital fusion of fingers and toes and small bone fusion

➢ Offices in France, Germany, Switzerland and U.S. (opened 2007 in Memphis, Tennessee; www.mmi-usa.com)
  ➢ Markets full line of shape memory and superelastic clips, screws, staples, etc. for foot/ankle and hand/wrist applications

META BIOMED CO., LTD.
Chungbuk, Korea
www.meta-biomed.com

➢ BoneMedik and BoneMedik-S Bone Void Fillers
  ✓ K070897

(Continued on page 4)
Newcomers...

(Continued from page 3)

- Resorbable coralline HA (BoneMedik-S contains ~1% silicon)
- Available in blocks and granules
- Indicated for use to fill bony voids or gaps...
  ➢ U.S. Patent 7,008,450 (also assigned to Korea Institute of Ceramic Engineering and Technology), “Porous hydroxyapatite containing silicon and magnesium, and a preparation method thereof”
  ➢ Focused mostly on dental materials/equipment and resorbable suture technologies

METASURG
Houston, Texas USA
www.metasurg.com

➢ Metasurg Subtalar Implant
  ➢ K070441
  ➢ Ti alloy implant for use in treatment of excessive motion of the talus relative to the calcaneus; for use in treatment of the hyperpronated foot and stabilization of the subtalar joint
  ➢ Also markets Ti6 Internal Fixation System

MONDEAL MEDICAL SYSTEMS GMBH
Tuttlingen, Germany
www.mondeal.de

➢ Extremity Bone Fixation System
  ➢ K072740

➢ Hand Contour System
  ➢ K071797
  ➢ Ti plates (straight, “T” shaped and condylar) and screws
  ➢ Intended to be used for the internal fixation of small bones including the hand and the foot

➢ Distal Radius System
  ➢ K071798
  ➢ Ti volar and dorsal plates in “T” shaped right and left hand configurations
  ➢ Intended for fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspect

➢ Also markets Ti mesh, hand distractor, etc. and numerous dental-related products

NANOTHERAPEUTICS, INC.
Alachua, Florida USA
www.nanotherapeutics.com

➢ Origen DBM with Bioactive Glass
  ➢ K062459
  ➢ Resorbable, malleable, putty-like bone void filler with human demineralized bone matrix (DBM) + calcium phosphor-silicate particulate material particles in porcine collagen carrier
  ➢ Available in syringe (20 cc or 5 cc)
  ➢ Indicated for use to fill bony voids or gaps...
  ➢ Granted exclusive worldwide orthopedic distribution rights to Orthofix
  ➢ U.S. Patent 7,063,748, “Methods for coating particles and particles produced thereby”

ORTHOGEM LIMITED
Oxford United Kingdom
www.orthogem.com

➢ Tripore
  ➢ Resorbable Tripore HA (100% HA), TriPore BP 90 (90% HA, 10% TCP), TriPore BP15 (15% HA, 85% TCP)
  ➢ Available in blocks and granules
  ➢ Indicated for use to fill bony voids or gaps...
  ➢ Developed proprietary, patented process for manufacturing synthetic bone graft
  ➢ Interested in discussing its technology with potential commercial or clinical partners

PENTAX CORPORATION
New Ceramics Division
Tokyo Japan
www.pentax.co.jp

➢ Apaceram Bone Graft Substitute
  ➢ K071912
  ➢ Resorbable synthetic HA
  ➢ Available in powder and blocks
  ➢ Indicated for use to fill bony voids or gaps...
  ➢ Available ex-U.S. for decades
  ➢ Developed Cellyard products – beads as carriers for cells; scaffolds and pellets as carriers in regenerative medicine applications like culturing of bone cells

RELIANCE MEDICAL SYSTEMS, LLC
Sandy, Utah USA

➢ Reliance VBS System
  ➢ K063637
  ➢ PEEK or Ti alloy spacers
  ➢ Intended for use in the thoracolumbar spine to replace a portion of a collapsed, damaged, or unstable vertebral body due to tumor or trauma; to be used with legally cleared anterior or posterior supplemental fixation devices and with bone graft

(Continued on page 5)
Newcomers...

(Continued from page 4)
SANACOR LLC
American Fork, Utah USA
➢ LowTop Pedicle Screw System
   • K070933
   • Posterior approach pedicle screw system

SOUTHERN SPINE, LLC
Macon, Georgia USA
➢ Anterior Cervical Stabilization System
   • K063764
   • Ti plates with or without tissue shields to cover the screws after implantation (allow screws to subside during the healing process)

SPINAL INSTRUMENTATION SIMPLIFICATION SYSTEMS, LLC
Maplewood, New Jersey USA
➢ Tension Band Anterior Spinal System
   • K071151
   • Stainless steel rods, hooks, wedges and bone (vertebral) and lockdown screws
   • Intended for unilateral screw fixation of the anterolateral thoracolumbar spine to provide stabilization of a spinal segment(s) as an adjunct to spinal fusion

SPINEFRONTIER, INC.
Beverly, Massachusetts USA
www.spinefrontier.com
➢ Dorado Intervertebral Body Cage
   • K072289
   • PEEK Optima-LT1 intervertebral body cage in various heights and footprints
   • Intended for posterior approach with autogenous bone graft in patients with degenerative disc disease at one or two spinal levels from L2-S1; to be used with supplemental spinal fixation system(s)
➢ Founded by spine surgeons
➢ Positioned as “Where Surgeons Innovate”

TAEYEON MEDICAL CO., LTD.
Incheon, Korea
www.tymedical.com
➢ 4S Spinal System
   • K063708
   • Ti alloy top-loading multiple component, posterior spinal fixation system with pedicle screws, rods, bolt, and a transverse (cross) linking mechanism
   • Also markets systems for restoration of disc height in treatment of vertebral fractures; standard and anatomic plating systems; unilateral, bilateral and ring external fixators for treatment of large and small bone fractures in upper and lower extremities and pelvis; retractors, bone mill and power instruments

THE 4TH COLUMN, LLC
Irvine, California USA
➢ Pillar Pedicle Screw System
   • K071743
   • Pedicle screw-based spinal fusion system

TRILLIANT SURGICAL
Carrollton, Texas USA
➢ 3S Hemi Toe
   • K072922
   • Uncemented CoCrMo alloy resurfacing implant
   • Intended to supplement first metatarsal phalangeal joint arthroplasty; indicated for hallux limitus or hallux rigidus, painful hallux valgus, revision of failed previous surgery and painful arthritis

VERTEBRATION, INC.
Powell, Ohio USA
www.vertebration.com
➢ XYcor Spinal Implant
   • K070082
   • Ti alloy VBR device with self-locking mechanism
   • Specifically designed for low profile, minimally invasive implantation
   • Available in 8 heights/1 mm increments
   • Intended for use in thoracic and/or thoracolumbar spine to replace a collapsed, damaged or unstable vertebral body resected or excised due to tumor or trauma
   • Intended for use with bone graft and supplemental internal fixation
➢ Surgeon co-founder

VERTIFLEX, INCORPORATED
San Clemente, California USA
www.vertiflex.net
➢ Vertiflex Spinal Screw System
   • K062670
   • Ti alloy, posterior, top-loading, non-cervical instrumentation system with fixed and polyaxial pedicle screws, rigid connecting rods
   • Introduced as the Silverbolt MIS Screw System in 2007
   • To serve as a platform for percutaneous and mini-open fusion procedures

(Continued on page 6)
Newcomers...

(Continued from page 5)

- Octane PEEK Vertebral Body Replacement
  - K070218
  - Intended to serve as a partial or total replacement of a vertebral body that is collapsed, damaged or unstable as a result of tumor or trauma

- Subsidiary companies in Germany and the Netherlands
- Also developing pedicle screw-based DynaBolt Dynamic Stabilization System delivered through the Silverbolt system, Superior titanium inter-spinous spacer (released ex-U.S. in 2007) and Oracle expandable retractor system

Members on the Move

Shawn T. Huxel, CEO & President, Core Essence Orthopaedics, LLC

In this Members on the Move, we are fortunate to be able to feature a member who not only co-founded one of the companies profiled on the previous pages but who also just so happens to be a serial entrepreneur with a number of orthopaedic start-ups under his belt.

Following stints in engineering and new business development for the likes of J&J Orthopaedics, Ethicon and the J&J Corporate Biomaterials Center from 1988 to 2001, Shawn Huxel moved out on his own. His first venture found him working as a consultant to emerging medical device companies. Then from 2002 to 2004, he served as President and General Manager of Osseus, LLC, a start-up with a novel cabling system for general fracture repair. In 2004, Shawn founded Xtremi-T, LLC, focusing on biodegradable implants for extremity fixation. Xtremi-T became part of Small Bone Innovations in early 2005 and Shawn was retained as SBI’s Worldwide Vice President of Technology and Business Development until January 2007, when he founded Core Essence Orthopaedics, LLC.

Shawn holds 27 U.S. patents and has a number pending. He earned a Bachelor of Engineering degree from Hofstra University with a specialization in Mechanical Engineering, an MS in Technology Management and an MBA from the New Jersey Institute of Technology.

Today, Shawn is CEO, President and co-founder of Core Essence Orthopaedics, LLC, a privately-held orthopaedic company focused on soft tissue and skeletal repair of the extremities. He can be reached at Shawn.Huxel@CEOrtho.com.

OrthoKnow (OK): At what point in your career did you begin to envision yourself as an entrepreneur?

Shawn Huxel (SH): My career has taken me through most facets of the medical device arena from cosmetic and reconstructive surgery, through urogynecology and finally into the world of musculoskeletal repair. I have always taken an entrepreneurial approach to problem solving as these exciting surgical fields have evolved. Even within a large corporation like J&J, I became an “intrapreneur” attempting to develop devices and businesses across numerous J&J device categories.

For instance, working with Indigo Medical in 2000, I developed a biodegradable stent technology targeted at the male urology marketplace. When the product was ready for clinical evaluation, the strategy of Indigo Medical shifted and this technology was without a commercial partner within the J&J family of companies. Ultimately we were successful in out-licensing this technology to a large player in Urology that may see it to the marketplace after clinical evaluations are complete.

OK: What was your primary motivation to leave the security of a large organization?

SH: I had a very strong desire to create a business that would dramatically impact people’s lives. Throughout my years with J&J, I took tremendous satisfaction in developing enabling solutions that addressed real unsolved problems. I led teams that developed products such as RigidFix™ at Depuy/Mitek, now a standard of care for hamstring tendon grafting, and an absorbable rivet technology sold through the Depuy/Codman organization under the brand CranioSorb™. Each of these developments spanned years of development and were ultimately transferred to their respective commercial partners for manufacturing, regulatory and marketing years later.

Often, the security of the large organization can stifle innovation simply because a sense of urgency does not exist and the impact of the success (or failure) is diluted by sheer critical mass. In many ways, I believe that large organizations such as J&J and, to a certain extent, even SBI (Small Bone Innovations) are most successful at marketing products that have already been developed and/or acquired.

Co-founding Core Essence Orthopaedics has given me the ability to quickly develop technologies

(Continued on page 7)
S. Huxel...
(Continued from page 6)

and launch them into our space through a sophisticated independent sales network. We can be nimble and develop these businesses in real time by driving sales at the front line.

OK: What was your main concern?

SH: Actually a very predictable answer — resources. As a portfolio or team leader in a corporate model, you have access to a seemingly endless supply of personal and cash capital. As a result, you are measured by how many people you use and whether you have used the money allocated to the program — basically a use ’em or lose ’em model.

In a start-up environment, the model is much different. We have finite resources, have to make decisions with incomplete information and take risks. If you are unsuccessful and you burn through your resources — that’s it, usually there isn’t someone to come along and pick up the pieces. This is what we live with every day.

OK: What patterns from the “corporate world” were you able to easily implement to your benefit? What corporate patterns did you seek to avoid?

SH: When I listen to corporate executives and the investment community (basically the “haves” from a capital perspective) there is a certain philosophy of “you get what you pay for” (what you can afford). This is a universal concept for both the corporate world and the capital markets. And I do agree with this to an extent. Yes, if you have a team of engineers and millions in capital, there is significant probability that a solution (at least one) will be created for the given problem.

As an entrepreneur, I like to pay for what I get. So, the focus is on the getting, not the paying. I strongly believe we will leverage the full potential of this company and our products by getting (and/or developing) technologies that will place our sales force and marketing engine in a position to succeed. As a result, we fully intend to use resources when we need them, not just because they are there.

OK: What do you miss about the corporate world, and what do you enjoy not having?

SH: What I miss and what I enjoy not having are one in the same. I miss the rich lunchtime discussions, but I enjoy not having the chatter in the cafeteria. I miss the diversity of opinions and perspectives, but not the paranoia. I miss the (collective) wisdom of the organization and I enjoy not ever hearing “…ten years ago we tried that and it didn’t work, so don’t bother.” I miss the seemingly endless resources but enjoy not having multiple “stakeholders,” thus forcing consensus for direction.

OK: Were there times when you doubted your decision?

SH: I’m not one to doubt or regret decisions. The key here is that I made a decision and acted upon it. You make an informed decision. If it was the right one, you live with it. If the result was less than expected, you adjust or adapt. Believe me, I have personally made some very bad decisions, learned from them and moved on as fast as possible toward the right decision. Doubts and regrets are barriers to decisions. If you are so caught up in wrong or poor decisions, you are wasting time and moving toward the very worst of decisions, the decision of “nondecision.”

OK: Life in a start-up can be particularly demanding, especially on family. How have you handled these issues?

SH: My wife, Alexa, and my two daughters, Katya and Kyra, have stood beside me in every aspect of the start-up life. When I first left J&J, before I could afford a multiyear office lease, I set up operations in the basement of my home. My family had no choice but to be intimately involved in this new life. Interestingly enough, they got it. Gone were the days of being out of the house at meetings for multiple days and nights at a time. Instead, I ushered the kids to school and then returned to work in my basement office. And, by example, when they returned, on our dining room table were color schemes of an instrument sterilization tray for them to choose.

Things are a little different now; I have an office outside of the home, I travel quite a bit and the girls are many years older, but I truly appreciate those grounding days during the transition and the support of my family and friends.

OK: What would you consider to be your biggest lesson learned, and your best single accomplishment?

SH: My biggest lesson learned is you can’t do it all. I have been fortunate to work with elite associates and elite surgeon/customers and the ability to call upon these colleagues as needed. Without these relationships, success in our industry is close to impossible. Taking an idea, whether it be a business concept or a transformational technology, to the marketplace requires relationships up and down the value chain — from the person running the manufacturing machine all the way to the patient.

(Continued on page 8)
relationships that I have put in place maintain the continuity of this cycle.

**OK:** What are the essential elements of a successful musculoskeletal start-up company?

**SH:** A true start-up musculoskeletal company requires an innate connection between the founders and the end customer. The founders must have a very rich understanding of the problems facing the customers and the ability to provide solutions to these problems. According to the AAOS, there are over 24,000 surgeons in their membership community. Adding in the additional customers of podiatric surgery, neurology, cranio/max and plastic/reconstruction, we can easily define a customer base of over 30,000 professionals working every day delivering care in the musculoskeletal field.

Now, we aren’t going to touch all of these customers, but we should always be cognizant that a truly successful transformational technology or business is one that crosses multiple specialties in utility and intuition.

Additionally, success is best measured through the sale of products. Without a sophisticated sales organization with existing relationships, the road to revenue is a tough haul. So, the essential elements must include the customer’s perspective, an intuitive approach that solves a problem, and someone to deliver the message on the street.

**OK:** Many universities offer courses in entrepreneurship. Can it be taught, or are entrepreneurs born?

**SH:** This is a classic question. I don’t believe that entrepreneurship can be taught, nor do I believe that you are born with it. The essence of the entrepreneur evolves throughout the life experiences of the individual. I don’t think that that kid who wakes up in the morning to collect his allowance will know the life ahead of him or her.

But, look around the corner at Johnny using dad’s lawnmower to mow the Smiths’ lawn for five bucks or Sally with her lemonade stand in the neighborhood and we see the essence of the entrepreneur. These two didn’t wake up one day and decide to do this, and I don’t think their parents forced it upon them. I believe they each had a purpose to get out of bed that day. My story was golf balls. Dad allowed me to tag along his golf games while paying me 35¢ to find golf balls in good condition. By following some of his errant shots, I became very acquainted with the “target rich” locations. Soon, my father could no longer afford to let me tag along. As a result, I took my efforts to the next level and set up an enterprise at the pro shop.

So, no, it can’t be taught or genetically fashioned. Many times it is simply the result of a situational evolution.

**OK:** What is your vision for your company’s future?

**SH:** In keeping with the context described above, I have surrounded myself with very talented, passionate associates. Both Alan and Jeff (Miller) bring decades of rich experience from manufacturing, building businesses, development and marketing. Our Founding Capital Members, aside from bringing capital, provide a broad perspective on what it is to be successful in this industry clinically, financially and organizationally. We are just now releasing our first three product families into the marketplace and are poised to launch two more portfolios by the end of 2008. We will be realizing cash flow from the operations in early spring while at the same time financing the next stage of our growth. We are looking forward to a bright future for Core Essence Orthopaedics. Whether through exit to a mid-to-large size strategic partner or through vertical integration into a small-cap orthopaedic company, the upcoming years will be exciting for our organization.

**OK:** What advice do you have for others who contemplate following in your footsteps?

**SH:** Be true to yourself. If it doesn’t feel right, don’t do it. Find something that feels right. I have been fortunate and have had the support needed to do what feels right on multiple occasions. When it stops feeling right, it’s time to adjust or move on.