We last wrote about upper extremities and power equipment in the November/December 2005 issue. (“Stryker Rules the Power Market; Smaller, Niche Players Position Themselves to Address Upper Extremities,” U.S. Orthopaedic Product News, November/December 2005.) Since that time, many existing companies have brought out some pretty cool technologies in these areas (e.g. Stryker’s Precision Oscillating Tip Saw and, of course, the spate of distal radius plates). At the same time, a handful of newcomers have gained FDA clearance for everything from traditional pins, wires and bone graft pellets to knotless suture anchors à la KFx Medical. We took note of high-speed power tool guru Anspach receiving clearance for a knotless suture anchor, as well.

Not every 510(k) will lead to a marketable product. Often, receipt of clearance simply sets the stage “just in case” the company decides to move forward and enter the U.S. with a product. Some products will live predominantly in a file, while others will undergo a number of design iterations prior to market introduction.

Regardless of intention, since October 2005, 17 companies have received their first 510(k) through FDA’s Orthopedic Advisory Committee for products that are either power-driven or could be used in upper extremity applications. This article provides a bit of information on them and their 510(k) clearances. (We included some sternal devices, too, if for no other reason than they don’t get much attention in many other forums.)

**Acute Innovations, LLC**
Hillsboro, Oregon USA
www.acuteinnovations.com
- **Acute Bone Screw**
  - K061206
  - Titanium screw in varying lengths
  - Available partially or fully threaded, cannulated or solid, with or without plate and/or washer
  - Intended for use in stabilization/fixation of fractures and for fusions and osteotomies
  - Also developing U-shaped rib plate
  - Acumed spin-off

**Axiom Orthopaedics, Inc**
Jersey City, New Jersey USA
www.axiomortho.com
- **Shoulder Resurfacing System**
  - K061862
  - Proposed design to incorporate cobalt chrome humeral heads for articulation with resurfaced or non-resurfaced glenoid fossa; interior surface coated with a plasma spray titanium substrate and a calcium phosphate coating
  - Indicated for use as a hemi shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable
  - Patents pending
  - Developing Fourth Generation shoulder platform

**Bioretic Ltd.**
Tampere, Finland
www.bioretic.com
- **ActivaPin and ActivaScrew**
  - K061164 (ActivaPin) and K062980 (ActivaScrew)
  - Resorbable poly(L-lactide-co-glycolide) devices
  - Indicated for fixation of bone fractures and for osteotomies, arthrodeses, etc.
  - Founded 1998, with focus on drug delivery products

**BK Meditech Co., Ltd.**
Kyunggi-Do, Republic of Korea
- **Pin Screw**
  - K061599
  - Stainless steel
  - For use in conjunction with rigid external supporting frame for immobilization of open and/or unstable fractures and where the soft tissue injury may preclude the use of other fracture treatments
  - Also markets external fixators, spine systems and prosthetics outside the U.S.

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**FISCAL FITNESS**

**Finland to Korea, Screws to Shaver Blades: New Companies Gain Access to U.S. Market for their Upper Extremity or Power Tools**

*Author: Shirley A. Engelhardt*
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Collagen Matrix, Inc.
Franklin Lakes, New Jersey USA
www.collagenmatrix.com
• Collagen Bone Healing Protective Sheet
  • K052041
  • Conformable, resorbable membrane matrix engineered from highly purified type I collagen derived from bovine Achilles tendon
  • Can be used either alone or in conjunction with internal fixation devices such as plates and screws
  • Intended for use with traditional rigid fixation for maintaining the relative position of weak bony tissue; for use alone for maintaining the relative position of bone grafts or bone graft substitutes in certain reconstructive procedures; and for cement restriction in total joint arthroplasty procedures. Not intended for use in the spine or for load bearing indications unless used in conjunction with traditional rigid fixation.
• OssiMend Bone Graft Material
  • K052812
  • Resorbable collagen mineral composite matrix (strips, pads, granules) comprised of bovine type I collagen (45 percent) + anorganic bovine bone mineral (55 percent)
  • Combined with autogenous bone marrow and intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure
  • Numerous dental and neurology clearances as well
  • Distribution agreements with Stryker for nerve cuff and dural substitute membrane products
• Founded 1997 to develop collagen-based technology for tissue repair and regeneration

Delta Surgical Instruments, Inc
Highland Mills, New York USA
• Pins and Wires
  • K060654
  • Various implant grade stainless steel (316L) pins and wires
  • Indicated for use in fixation of bone fractures and bone reconstructions or as a guide/aid for insertion of other medical devices

David J. Slutsky M.D.
South Bay Hand Surgery Center
Torrance, California USA 90503
• Fragment Specific Fixator
  • K052498
  • Lightweight, radiolucent construct attaches to self drilling bone pins
  • Intended for use in a nonjoint bridging configuration (allowing for immediate wrist motion during the fracture healing period of six to eight weeks) or in a joint bridging manner to provide ligamentotaxis to obtain and maintain the fracture reduction during the healing period.

Eberle Feinwerktechnische Systeme GMBH & Co. KG
Wurnberg, Germany
www.efs-eberle.de
• Eberle Shaver System C2 and Shaver Blades
• K061134
  • Power instrument system with control unit, footswitch, hand-piece and accessories
  • Designed for use in arthroscopic procedures
  • Also markets arthroscopes, handheld instruments, interference screws and shaver blades for a variety of other companies' systems outside the U.S.

Gexfix USA Inc.
Boca Raton, Florida USA
www.gexfix.ch
• Geneva External Fixator (Gexfix)
  • K052605
  • Small and large fixators for distal radius, wrist, leg, ankle and pelvic applications and a hybrid system for proximal humerus and tibial fracture applications
  • Indicated for use in fracture fixation, osteotomy, arthrodesis, correction of deformity, bone reconstruction and revision procedures where other devices have been unsuccessful.
• Founded 2004 by “professionals from the orthopaedic trauma industry”

Gold Standard Orthopaedics LLC
Louisville, Kentucky USA
• GSO Bone Fixation Fasteners
  • K063589
  • Stainless steel smooth or threaded pins and wires and cortical, cancellous 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 so that traction may be applied to the skeletal system; not indicated for spinal fixation

Intai Technology Inc.
Ontario, California USA
(Intai Technology Corporation, Taiwan)
www.intai.com.tw
• Intai Bone Plate and Bone Screw System
  • K063020
  • Mini, small and large configurations of stainless steel land titanium plates and screws
  • Intended for use in fixation of fractures in clavicle, pelvis, scapula, calcaneus, long bones (humerus, ulna, radius, femur, tibia, and fibula) and small bones (metacarpals, metatarsals and phalanges).
  • Also received FDA clearance for DHS and DCS plate and screw systems for treatment of femoral fractures

Internal Fixation Systems
Miami, Florida USA
• IFS Cannulated Bone Screw
  • K061620
  • 316L stainless steel self-tapping, self-drilling, partial or fully threaded screws in a variety of diameters and lengths
  • Intended for use in treatment of bone fractures, such as

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fractures of the tarsals and metatarsals, and for metatarsals and phalangeal osteotomies and arthrodesis of hand and foot

KFX Medical
Carlsbad, California USA
www.kfxmedical.com
• KFx Knotless Fixation System
  • K061294
  • aka SutureCross Knotless Anatomic Fixation System
  • Features KFx Nail Bone Anchor + KFx Suture Lock Bone Screw Anchor + optional KFx Targeting Grasper
  • Intended for use in fixation of soft tissue to bone during rotator cuff repair
  • To be offered at select U.S. Centers of Excellence

Koby Surgical
Houston, Texas USA
www.metasurg.com
• Koby Surgical Internal Fixation System
  • K060026
  • Ti6Al4V cannulated or non-cannulated bone screws in varying diameters and lengths
  • Intended for use to aid in the fixation of fractures and for non-unions, arthrodeses and osteotomies of the small bones in the hand and foot
  • Appears to be focused on foot surgery

Medicon E.G.
Tuttlingen, Germany
www.medicon.de
• Stern-a-Fix Sternal Closure System
  • K053624
  • Titanium plates and self-drilling, locking, standard and emergency bone screws
  • Intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures
  • Also markets various orthopaedic, craniomaxillofacial and spinal power and handheld instruments
  • Numerous dental and neurology product clearances as well, including high speed drill, implants and clips

Newclip Technics
Haye-Fouassiere, France
www.newcliptechnics.com
• Distal Radius Locking Plating System
  • K061917
  • Various Ti6Al4V plates with locking screws, locking pegs, locking threaded pegs and cortical screws
  • Intended for use in fixation of intra- and extra-articular fractures as well as distal radius osteotomy
  • Also markets specialty plates and screws outside the U.S.

Praesidia S.R.L.
Bologna, Italy
www.praesidia.it
• Flexigrip Sternal Closure System
  • K063009
  • Specially-shaped nitinol shape memory alloy clip that goes around (but does not completely encircle) the sternum
  • Intended for use in closure or repair of the sternum after sternotomy, fracture or dehiscence
  • Also markets (outside the U.S.) medical disposables (e.g. fluid capture, sterile covers, lavage kits, etc.)

Promed Advance Technology Co., Ltd.
Taipei, Taiwan
• Osteo-Link Bone Void Filler Pellets
  • K060809
  • Resorbable calcium sulfate pellets
  • Indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure (e.g. extremities, spine and pelvis)

Rema Medizintechnik GMBH
Tuttlingen, Germany
www.rema-surgery.com
• Arthroscopic Shaver Blades
  • K060172
  • For use with a variety of companies’ shaver systems
  • Intended for shaving, cutting and abrading of bone and tissue during arthroscopic procedures
  • Also markets a variety of instruments for minimally-invasive surgical procedures

This array of companies serves to reinforce what has always struck me about orthopaedics. The companies that find their way into the market are anything but samey or predictable. They hail from all over the planet and bring forth manufacturing expertise, design ingenuity, a passion for orthopaedics, an entrepreneurial bent, a dream of a better product or some marvelous combination thereof. I keep my eye on the 510(k) roster for a lot of reasons, not the least of which is its ability to clue me into what could be the next homerun company or product.

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