Here are 35 spine device companies that have engaged in research and development and have received FDA clearances and patents in the past year. These companies are almost exclusively focused on the spine market. We will be updating this list periodically throughout the year. If you have questions, please contact Carrie Pallardy at cpallardy@becker-healthcare.com.

1. Accel Spine
Accel Spine, based in Dallas, is a medical device company serving the spine market. The company offers a range of products including cervical and thoracolumbar devices, a minimally invasive system, biologics and non-narcotic pain management device. The cervical products include an interbody fusion device, an anterior plate system and a posterior fixation system. The thoracolumbar products include an open fixation system and an interbody device. Accel Spine’s Picasso is a minimally invasive system created to treat deformity and degenerative conditions of the lumbar and thoracic spine. Accel Spine received a total of eight FDA clearances last year.

2. Alliance Spine.
Alliance Spine, based in San Antonio, is a company created from the collaboration of the academic world, spine surgeons and manufacturers. The company works to take a product idea from the research stage to the manufacturing stage and finally to the hands of surgeons. The company has an interbody line of products and a biologics product line. Alamo C, a cervical intervertebral body fusion device, is manufactured from PEEK Optima and is designed to create a large graft area allowing for optimal bone graft placement. The company’s biologics include Cyclone, Osteo Strip and SwannShidi. Cyclone is a bone marrow concentrate system. Osteo Strip is a compressive graft material specifically designed for spinal fusions and orthopedic surgeries. SwannShidi is a vertebral bone marrow aspiration device. Alliance Spine is also working on developing a full line of PLIF and TLIF interbody devices and a cranial plate. In 2012, the company received FDA 510(k) approval for two interbody Alamo devices.

3. Alphatec Spine
Alphatec Spine, headquartered in Carlsbad, Calif., is a medical device company that produces devices intended to treat spine disorders and improve the quality of patient life. The Alphatec Spine product portfolio has a wide range of devices including thoracolumbar, cervico-thoracic, interbody, minimally invasive and vertebral compression fracture treatments. The company also produces biologics and solutions for the aging spine. The company recently received FDA 510(k) clearance for Pegasus, an anterior anchored cervical interbody device, and ILLICO FS Facet Fixation System, a minimally invasive device that eliminates the need for a pedicle screw and rod constructs during the immobilization of spinal segments. Alphatec Spine reported a nearly 7 percent increase in global revenue for the fourth quarter of 2012, as compared to the fourth quarter of 2011.

4. Amedica
Amedica, based in Salt Lake City, is a medical device company that creates silicon nitride
spinal and arthroplasty applications. Amedica is currently the only company with FDA clearance to create and market implants made from silicon nitride. The company’s products include Valeo Interbody Fusion Devices, Facet Fixation, Preference 2 Pedicle Screw System and Origin Orthobiologics. Amedica expanded its executive team in January with the addition of legal, compliance, marketing and sales executives. In February, the company received a patent for a silicon nitride total disc implant to treat back and neck pain.

5. Apollo Spine
Apollo Spine, based in New Port Beach, Calif., is a company centered on serving the spine industry with solutions for scoliosis, trauma, degeneration and spondylolisthesis. The company’s product portfolio includes the Eclipse-C Cervical Interbody Spacer, the Eclipse-L Lumbar Interbody Spacer, the Comet Cervical Plate and the Zenith Pedicle System. Apollo Spine designs the products to be minimally invasive, to improve current fusion treatments and to preserve motion. The company is currently working on developing its Venus Facet Screw and its Jupiter Modular Spacer System, which will serve as a treatment for patients suffering from deformity or degenerative conditions.

6. Ascendx Spine
Ascendx Spine, based in Winter Park, Fla., is a medical device company focused on the development and marketing of VCF Repair Systems and the Acu-Cut Vertebral Augmentation System, both designed to treat vertebral compression fractures. A prospective, multicenter clinical study conducted on the results of the Ascendx VCF Repair System found patients to have considerable lessening of pain and improvement of function. Both the VCF Repair Systems and the Acu-Cut Vertebral Augmentation System have received FDA 510(k) clearance and the CE Mark.

7. Back 2 Basics Spine
Back 2 Basics Spine, based in Cleveland, is a medical device company that primarily focuses on providing lumbar fusion with interbody devices in order to treat degenerative conditions of the spine. The company plans to submit its Dymaxeon spine system to the FDA for 510(k) clearance. The Dymaxeon spine system, comprised of a rod and screw with hooks designed to fit and support the spinal column, will be geared towards addressing not only degenerative spine conditions, but trauma and neuromuscular issues as well. Back 2 Basics Spine believes in creating an affordable high quality system for hospitals and surgeons.

8. Captiva Spine
Captiva Spine, based in Jupiter, Fla., is a medical device company that strives to place solutions for procedures in the hands of spine surgeons. Captiva Spine products include the CapLOXII spinal system, the FuseLOX lumbar cage, the Pivotec TLIF cage, the SmartLOX cervical plate system, the FuseLOX cervical cage and the TowerLOX spinal system. In 2011, the Pivotec TLIF device, a controlled pivotal delivery system, was awarded a patent and the CapLOXII spinal system received FDA 510(k) clearance. The TowerLOX spinal system, a cannulated pedicle screw system, received FDA clearance in 2012.

9. Centinel Spine
Centinel Spine, based in New York and West Chester, Pa., is a biomechanics company that works to translate surgeons’
ideas into products that can be effectively used in the field of spine surgery. The company’s products include the Stalif TT, the Stalif C and the Stalif Midline. Each product has undergone a biomechanical study to ascertain its efficacy. The biomechanical studies of the Stalif TT and the Stalif C found that each functioned well as a truly stand alone device. The Stalif Midline was designed to avoid posterior surgery, create stable fixation, and restore disc height and to be MRI compatible. The biomechanical study of the Stalif Midline compared its flexibility to that of Centinel Spine’s Stalif TT and found the two devices to be on equal footing. Centinel Spine prides itself on basing its products on biomechanical principles, rather than ease of use alone.

10. ChoiceSpine
Choice Spine, based in Knoxville, Tenn., is a spinal technology company that aims to work with orthopedic and spine surgeons to create the products they need. The company holds a number of patents and produces devices that are designed to treat six different spine conditions. Choice Spine’s cervical spine products include the FALCON and the STEALTH Cervical Fusion Devices. The company also has two thoracolumbar products, a device designed to treat patients with scoliosis, an anterior spinal clip system and several lumbar products. One of the company’s newest products is the STARFIRE Pedicle Screw System.

11. Globus Medical
Globus Medical is an Audubon, Pa.-based spinal implant manufacturing company with minimally invasive, motion preservation, cervical intervertebral fusion, thoracolumbar and bio materials products. For the year 2012, the company’s sales were $386 million, up 16.4 percent from the previous year. Net income increased from $60.8 million in 2011 to $73.8 million in 2012, a 21.5 percent increase. Globus Medical is currently conducting several clinical trials. The company just completed a study of their TRIUMPH Lumbar Disc, a cobalt chrome alloy articulating disc intended for reconstruction of the spinal disc.

12. Invibio
Invibio, based in West Conshohocken, Pa., provides biomaterial solutions to the medical device market. The company offers biocompatible polymers including PEEK-OPTIMA polymer and compounds, MOTIS polymer, ENDOGLIN composite and PEEK-CLASSIX polymer. Invibio biocompatible polymers have been used in devices such as the OSIMPLANT ARAMIS surgical disc prosthesis, Aesculap EnduRo Rotational Knee System and Kelyniam Global Custom Skull Implants. In 2009, Invibio’s PEEK-OPTIMA biomaterial received a Spine Technology Award for its innovation in the biomaterial field.

13. K2M
K2M, based in Leesburg, Va., is a medical device company concentrated on creating solutions for complex spinal treatments and procedures. The K2M product line includes solutions for spine deformity, trauma, tumors and degenerative lumbar. The company also manufactures minimally invasive devices, cervical devices, interbody devices and biologics. K2M also offers platform technologies including MESA Technology, RANGE Complex Spine Technology, tifix Locking Technology and Rail 4D Technology. K2M has additional offices in the UK, Germany, Austria and Switzerland. In 2012, the company introduced their product portfolio to the Italian market.
14. Lanx
Lanx, based in Broomfield, Colo., is a medical device company that aspires to work with spine surgeons to produce efficient products that better patient outcomes in fixation and fusion procedures. The company recently added the Timberline Lateral Fusion System, the Epic Anterior Thoracolumbar Plate, the Durango Stand-Alone ALIF System and the Concero Facet Screw System to its product line, which already contained biologics, several different systems and a number of different spacers. In 2012, Lanx was granted a patent for the minimally invasive ASPEN Fusion System and announced the results of a clinical study that found a 94 percent fusion rate with the ASPEN system.

15. LDR
LDR, founded in Troyes, France and headquartered in Austin, Texas, is a global medical device company focused on designing and commercializing novel and proprietary surgical technologies for the treatment of patients suffering from spine disorders. The primary LDR products, which they refer to as their exclusive technologies, are based on the VerteBRIDGE® fusion platform and the Mobi non-fusion platform, both of which have applications in the cervical and lumbar spine. LDR believes that the VerteBRIDGE and Mobi exclusive technologies enable products that are less invasive, provide greater intra-operative flexibility, offer simplified surgical techniques and promote improved clinical outcomes for patients. The Mobi-C Cervical Disc from LDR was the first cervical disc to undergo a concurrent, multi-center IDE trial for one and two-level cervical disc replacement and is currently under review by the FDA for both indications. In addition to Austin and Troyes, LDR has regional offices in Germany, Spain, China, Korea and Brazil.

16. Life Spine
Life Spine, a company based in Hoffman Estates, Ill., develops, manufactures and markets products that are intended for minimally invasive spine surgery. The Life Spine product portfolio includes anterior and posterior cervical, thoracolumbar and interbody products. The company recently announced the limited release of the CENTRIC Lateral Retractor System, which offers controlled blades and an open frame for optimal visual access during lateral approach spine surgery.

17. Mazor Robotics
Mazor Robotics, based in Orlando, creates robotic guidance systems designed to aid in surgeons in performing spine surgery. The company’s premier product is the Renaissance surgical system, which was developed for maximum precision and safety. Thus far, the Renaissance system has been used by surgeons to place over 15,000 implants. The system can be used in conjunction with spinal procedures including biopsies, pedicle screws, osteotomies, spinal deformity correction and a number of thoracolumbar approaches. Mazor Robotics also aims for the Renaissance system to be used in minimally invasive procedures, to lessen radiation exposure for patients and to produce consistent, optimal results. A clinical trial found the system to provide 98.3 percent accuracy in a study of 3,271 implants in 635 cases.

18. NLT Spine
NLT Spine is a device company that works to provide the spine industry with non-linear spinal solutions. NLT Spine is headquartered in Israel and opened a US office in Dedham, Mass., in January 2013. The company focuses on minimally invasive solutions and has a product portfolio of issued and pat-
ent-pending devices designed to treat degenerative spinal conditions. The PROW FUSION, designed for TLIF procedures, is designed to allow more bone graft volume within the implant than allowed by current devices. The PROW FUSION is the first clinical application of the company’s non-linear technology platform that has been introduced to the US. The company plans to build on that platform and provide products that address several spine pathologies. NLT’s discectomy system, eSPIN, is the company’s most recent product to receive FDA 510(k) clearance.

19. NuVasive
NuVasive, based in San Diego, is a medical device company that develops minimally invasive spine products and procedures, including the eXtreme Lateral Interbody Fusion system, which opened the door to lateral approach spine surgery. The company’s product line includes over 75 products. NuVasive offers lumbar products, thoracic products, cervical applications, neuromonitoring services and a line of biologics. NuVasive and the Society of Lateral Access Surgery are currently sponsoring a clinical trial of the company’s XL TDR device designed to treat degenerative disc disease. NuVasive has offices in Australia, Japan, Singapore, UK, Germany, Puerto Rico, Paramus and the United States.

20. Pioneer Surgical Technology
Pioneer Surgical Technology, based in Marquette, Mich., was founded by Matthew Songer, MD, when he created the Songer Spinal Cable. Pioneer Surgical Technology now provides devices for the spine, orthopedic, cardiothoracic and biologics fields. The company currently offers cervical, thoracolumbar, lateral and specialty instruments to service the spine market. The company’s NuNec Cervical Disc Arthroplasty reached 2,000 successful implantations last year. Pioneer Surgical Technology approaches all of their products from a vertical integration standpoint, aiming to take an idea from the design stage to the final stages of packaging.

21. Precision Spine
Precision Spine is a spine device company based in Parsippany, N.J., and the parent company of Spinal USA and Precision Medical. Led by President Richard Dickerson, the company gained FDA clearance for the Mini-Max™ULIF Spine System in December, intended for use with the SureLOK™ Pedicle Screw System. Precision Spine products, designed for cervical and thoracolumbar spine procedures, include several surgical systems. Precision Spine also announced a partnership late last year with Stephen Cook, PhD, to develop spinal implants with magnetic technology. The company also carries interbody devices, biologics and spinal bracing products. Precision Spine seeks to serve hospitals, neurosurgeons and orthopedic surgeons.

22. SI-BONE
SI-BONE, based in San Jose, Calif., is a medical device company that began as an offshoot of INBONE Technologies, which produced the ENDO-FUSE Intra-Osseos Fusion System. SI-BONE focuses on providing minimally invasive solutions for the treatment of the sacroiliac joint. The company’s iFuse Implant System is designed to provide an alternative to the traditional SI joint fixation and fusion treatments of degenerative sacroiliitis and sacroiliac joint disruption. The iFuse Implant System received FDA 510(k) clearance in 2011 after undergoing significant changes. In 2012, the company announced that 5,000 patients had been treated with the iFuse Implant Sys-
tem. SI-BONE is managed by a combination of executives from orthopedic and spine companies including INBONE, Medtronic and Kyphon.

23. Spinal Elements
Spinal Elements, headquartered in Carlsbad, Calif., designs and markets products for the spine industry. The company was founded in 2003 and received its first product clearances a year later for Lucent and Crystal. Lucent is a lumbar interbody system and Crystal is a PEEK cervical interbody system. Since then the company’s product line has expanded to include the MOSAIC cervical implant system, SAPPHIRE anterior cervical plate system, LOTUS posterior cervical-thoracic fixation system and five lumbar systems in addition to LOTUS. The company has also opened a biologics product line with the HERO ALLOGRAFT. The net proceeds from HERO ALLOGRAFT sales are donated to charities that support children with life-threatening medical conditions.

24. Spineart
Spineart has offices in Geneva, Switzerland, Irvine, Calif., and New York. The company develops and delivers fusion, motion and MIS implants to the spine industry. The company’s motion implants include the Baguera Cervical Disc Prosthesis, the Baguera Lumbar Disc Prosthesis and the Yoda Dynamic Posterior Device. Spineart fusion products include the Juliet PLIF and ALIF Cages, Romeo 2 Posterior Osteosynthesis, Tryptik Cervical Modular Cage-Lift, Tryptik Cervical Cage, Tryptik Cervical Plate and Tryptik Cervical Laminoplasty Staple. The Spineart MIS devices include the Romeo 2 Posterior Axel Device, Romeo 2 Minimally Invasive System, Juliet Olif Cage and Juliet TLIF Cage. Spineart recently announced that 8,200 of its Baguera Cervical Disc Prostheses have been implanted worldwide.

25. SpineGuard
SpineGuard, headquartered in St. Mandé, France and San Francisco, focuses on its line of PediGuard products, which includes Classic PediGuard, Curved PediGuard and Cannulated PediGuard. PediGuard is a handheld, wireless pedicle probe designed to ensure safe pedicle screw placement. The device uses the electrical conductivity of tissue to warn surgeons of possible vertebral cortex perforations during pedicle screw placement. Various clinical trials conducted on the device have found 97 percent screw placement accuracy, 15 percent of time saved during screw placement and 25 to 30 percent reduction of patient exposure to radiation during pedicle screw placement. In July 2012, SpineGuard reported 20,000 spine procedures had been performed with the use of PediGuard.

26. Spine Frontier
Spine Frontier, headquartered in Beverly, Mass., is a medical device company that was created by spine surgeon Kingsley R. Chin, MD, and began with the launch of the FacetFuse screws. The company’s Less Exposure Surgery product portfolio includes the SpineFrontier Trio, Facet Infuse and Inspan. FacetFuse is a minimally invasive screw system designed for posterior surgical procedures including trauma and degenerative diseases. The Inspan Process Plate System is a posterior non-pedicle, supplemental system for the non-cervical spine. The S-Lift is designed for intervertebral fusion in patients with degenerative disc disease. All three systems are patented.

27. Spineology
Spineology, based in St. Paul,
Minn., was founded in 1996 by spine surgeon Stephen Kuslich, MD. The company focuses providing the spine industry with products for minimally invasive procedures. Spineology’s first product was OptiMesh, a deployable mesh pouch that is designed to maintain the position of bone graft material within a vertebral defect and allow surgeons to treat these defects percutaneously or with minimal invasion. Since OptiMesh, the company has added the Threshold Pedicular Fixation System, Rampart Interbody Fusion System, SOAR Retractor System, Prime Liquid Tissue Matrix, Armor Amniotic Wound Covering, CapLOX Spinal System, MTF G2 Allograft and Capture Facet Fixation System to its line of minimally invasive minded products.

29. Spine Surgical Innovations
Spine Surgical Innovations, based in Easton, Mass., is a minimally invasive spine device company. The company centers on its Holmed Swivel Port System and a full line of spine surgery instruments, which can be used in lumbar and cervical spine procedures. The company’s product portfolio includes general instruments, distractors and compressors, pedicle instruments, rod instruments, torque instruments and several MIS systems. In 2011, Spine Surgical Innovations launched the Hummingbird series, a series of minimally invasive surgery light tubes, which is designed to attach to the Swivel Port MIS Retractor and provide the best possible lighting without interfering with surgeons’ movements.

30. Spine View
Spine View, based in Fremont, Calif., is a medical device company that focuses on the development and commercialization of devices and systems intended for use in spine surgery. The company’s systems include the enSpire Surgical Discectomy System, the Flex MIS Surgical Discectomy System, the enSpire Interventional Discectomy System and the SpineView MIS Decompression System. Spine View technologies aspire to be used in minimally invasive procedures and are created to treat conditions such as spinal stenosis, degenerative disc disease and herniated discs.

31. Spine Wave
Spine Wave, based in Shelton, Conn., is a medical device company concentrating on developing and marketing products in the spine field. The company offers the StaXx XD Expandable Device, StaXx XDL Expandable Device, Sniper Spine System, CapSure PS3 Spine System, Accent Cervical Spacer system and Ni-Lock Anterior Cervical Plate System to the US market. The StaXx XD Expandable Device and the NuCore Injectable Nucleus are available outside of the US. In 2011, Spine Wave received FDA clearance for its StaXx XDL Expandable Device and launched its cervical product line. The StaXx Expandable Device is a vertebral body re-
placement device designed to minimize bone resection, nerve root retraction and soft tissue damage.

**SpineWave**

32. **TranS1**
TranS1, headquartered in Raleigh, N.C., is a medical device company that directs its energy towards designing, developing and manufacturing device solutions for degenerative conditions of the lumbar spine. The company’s product portfolio includes AxiaLIF PLUS expandable implants, a presacral access kit and discectomy tools. The company also offers biologics, the VEC-TRE facet fusion system and the VEO Lateral System. The company’s AxiaLIF system recently received a Category 1 CPT code beginning in 2013. The company also recently acquired the medical device company Baxano, based in San Jose, Calif.

33. **Wenzel Spine**
Wenzel Spine, based in Austin, Texas, is focused on providing the spine market with alternatives to traditional spine fusion techniques and devices. The company’s key product is the VariLift L, which is a stand-alone FDA cleared device that once in position expands from a cylindrical shape to a wedge shape. The device is designed primarily for minimally invasive procedures. Last year, the company announced that 26,000 VariLift devices had been implanted across the world. Six clinical studies have been conducted to study the VariLift device and the most recent study found a fusion rate of over 90 percent.

34. **X-spine**
X-spine, based in Miamisburg, Ohio, is a spine implant company driven to create intuitive, next-generation devices. The X-spine line of spinal devices includes the AXLE Interspinous Fusion System, FIXCET Facet Fixation System, Calix and Calix PC Intervertebral Fusion Systems, Butrex Buttress Plating System, SPIDER Cervical Plating System, HGraft Spinal Allograft System and FORTEX and X90 Pedicle Screw Systems. In November 2012, the company gained FDA clearance for its Fortex CoCr Rod System and the Certex Cervico-thoracic Fixation System. X-Spine has received FDA clearance for six of its products within the past two years.

35. **Zyga Technology**
Zyga Technology, based in Minneapolis, is a minimally invasive spine device development and marketing company. The Simmetry system and the GLYDER system are the company’s chief products. The Simmetry is a sacroiliac joint fusion system. This system is designed to provide joint fixation, minimally invasive lateral access, bone graft delivery to the prepared joint and decortication and cartilage removal of the joint. Zyga Technology is currently developing the GLYDER, which is designed as a minimally invasive facet resurfacing system that will function as non-fusion therapy for painful facet joints. The GLYDER system is currently undergoing clinical investigation and has not yet been approved by the FDA. In 2012, Zyga Technology received $25 million in Series C financing. Versant Partners, Split Rock Partners and MB Venture Partners are the company’s largest investors.