**NEW DRUGS**

**Agriflu Seasonal Influenza Vaccine**

The FDA has granted an accelerated approval for Agriflu vaccine (Novartis Vaccines and Diagnostics, Italy) for people 18 years of age and older to prevent disease caused by influenza virus subtypes A and B. The vaccine is given as a single injection in the upper arm and is available in a single dose. The prefilled syringes do not contain preservatives.

Agriflu is not designed to protect against the 2009 H1N1 influenza.

Common side effects have included pain, injection-site swelling and redness, headache, muscle aches, and malaise. People with severe or life-threatening allergies to eggs from chickens, or to any other substance in the product, should not receive this vaccine.

Source: FDA, November 27, 2009

**Kalbitor for Hereditary Angioedema**

Ecallantide (Kalbitor, Dyax), a subcutaneously injected liquid, has been approved for the treatment of sudden and potentially life-threatening fluid buildup that can occur in people with hereditary angioedema (HAE), a rare genetic condition. The drug is indicated for patients 16 years of age and older.

HAE is caused by a defect in the C1 esterase inhibitor, a protein that regulates the immune system and blood clotting. Impaired functioning of this blood protein can lead to rapid swelling of the face or other parts of the body, which may result in permanent disfigurement, disability, or death. Swelling of the digestive tract may cause severe abdominal pain, nausea, and vomiting; airway swelling raises the risk of suffocation.

Ecallantide is reviewed in this month’s Pharmaceutical Approval Update feature on page 52.

Source: FDA, December 3, 2009

**Chenodal Tablets Now Available for Gallstones**

Manchester Pharmaceuticals has announced the availability of chenodiol 250-mg tablets (Chenodal). Approved by the FDA on October 22, 2009, the tablets are indicated for patients with gallstones who cannot undergo surgery because of disease or advanced age.

Prescriptions are being dispensed to patients exclusively through Centric Health Resources, a specialty pharmacy company. Patients and physicians may call Centric to place their first order (phone: 866-758-7068).


**Generic Aricept for Alzheimer's Disease–Related Dementia**

The first generic versions of Aricept (donepezil HCl) orally disintegrating tablets are now available from Mutual Pharmaceutical of Philadelphia. Donepezil is indicated for the treatment of dementia related to Alzheimer's disease.

The disintegrating tablets are available in strengths of 5 mg and 10 mg; the tablets dissolve on the tongue and are a benefit for patients with difficulty in swallowing.

Source: FDA, December 15, 2009

**New Indication**

**Zyprexa Tablets for Two Disorders in Adolescents**

The FDA has approved olanzapine tablets (Zyprexa, Lilly) for the treatment of schizophrenia and manic or mixed episodes associated with bipolar I disorder in adolescents 13 to 17 years of age.

The revised prescribing information states that clinicians should consider the increased potential for weight gain and hyperlipidemia in adolescents, as in adults, and the potential for long-term risks associated with this drug. In clinical trials, adolescents, like adults, tended to experience increased sedation and higher levels of prolactin and hepatic transaminase. The recommended starting dose for adolescents is lower than that for adults.

Drugs for pediatric schizophrenia or bipolar I disorder should be prescribed only after a thorough diagnostic evaluation and careful consideration of the risks involved with treatment. The label also mentions the need to include psychological, educational, and social interventions for pediatric patients.

Sources: Eli Lilly, December 4, 2009

**New Formulations**

**Small Vial of Insulin For Hospital Use**

Eli Lilly has introduced a small vial of insulin (3 mL, or 300 units) for hospitalized diabetic patients in the U.S. The new size is intended for insulin lispro injections of recombinant DNA (rDNA) origin (Humalog) and regular insulin human injections of rDNA origin (Humulin R-U100).

A typical vial of insulin contains 10 mL (1,000 units). The company will continue to provide the traditional 10-mL vial as well as additional deliveries to hospital patients, including the Humalog Kwik-Pen, which comes prefilled with Humalog insulin, and the original Humalog prefilled pen.

Sources: Medical Devices Business Review, December 8, 2009; Eli Lilly

**Zyprexa Injection for Adults With Schizophrenia**

An extended-release olanzapine injectable suspension (Zyprexa Relprevv, Eli Lilly) has been approved for the treatment of schizophrenia in adults in the U.S. This approval was based on data involving 2,054 patients.

Zyprexa tablets and Zyprexa Zydis orally disintegrating tablets are already...
DRUG NEWS

H1N1 Children’s Flu Vaccine Recalled: Loss of Potency

Sanofi-Pasteur has recalled about 800,000 pediatric doses of its vaccine against pandemic H1N1 influenza because of a 10% decrease in potency, according to the Centers for Disease Control and Prevention (CDC). The recall does not affect any of the vaccine for adults or products from other manufacturers.

The prefilled syringes that were recalled are for young children from 6 months to 3 years of age.

The recalled doses come from four lots of 0.25-mL prefilled syringes for pediatric use in 10-packs (lot UT023DA, UT028DA, and UT028CB) and 25-packs (lot UT030CA). There were no safety concerns; all lots passed pretesting for purity, potency, and safety.

Vaccine strength can sometimes decline with time, the CDC explained. The antigen content is only slightly below the specified range but was still expected to be protective. The vaccines lost strength a few weeks after they had been shipped.

Young children are supposed to receive two doses about a month apart. Health officials didn’t think that the children needed to get vaccinated again, even if they had received two doses from the recalled lots.

The vaccine has been available since early October. Since then, manufacturers have released about 95 million doses for distribution in the U.S.

The problem seems to have affected only pediatric prefilled syringes. It is thought that the antigen might have stuck to the walls of the syringes. In February 2009, Novartis had recalled five lots of seasonal flu vaccine packed in prefilled syringes under similar circumstances.

Sources: Med Page Today; Associated Press, December 15, 2009

Chronic Diarrhea May Indicate Zollinger–Ellison Syndrome

Chronic diarrhea that disappears when patients take a proton pump inhibitor (PPI) could be a sign of Zollinger–Ellison syndrome, say physicians from Saarland University Hospital in Hamburg, Germany.

In a patient with chronic, painless diarrhea for three years, a colonoscopy had revealed no pathology, and a diagnosis of irritable bowel syndrome was assumed. The patient was not taking any medications regularly, and he had no family history for endocrinopathies or cancer.

Physical examination, lower gastrointestinal (GI) endoscopy, and serial biopsies were unremarkable. Upper endoscopy revealed low-grade esophagitis, diffuse gastritis, and multiple superficial postbulbar ulcers. Gastric pH was below 2. Histological examination indicated Helicobacter pylori—negative hyperplastic gastritis. Duodenal biopsies indicated villous atrophy and crypt hyperplasia. Fasting gastrin was 217 pg/mL (the normal value is below 150 pg/mL).

After the patient started PPI therapy at double the standard dose, the diarrhea ceased completely for the first time in three years. This result, as well as the endoscopic findings, supported a clinical diagnosis of Zollinger–Ellison syndrome despite ambiguous gastrin levels.

After the PPI was withdrawn, tests failed to reveal the cause of the excessive gastrin production. However, an endoscopic sonogram suggested a duodenal wall gastrinoma and an isolated liver metastasis. After undergoing pancreaticoduodenectomy and liver metastasis resection, the patient remained tumor-free for six years.

The clinical diagnosis of Zollinger–Ellison syndrome is difficult to make because its signs and symptoms resemble prevalent GI disorders, such as gastro-
esophageal reflux disease (GERD) and chronic diarrhea. GERD is often the most prominent symptom, because excessive gastric acid causes high intestinal volume loads and mucosal injury.

PPIs may delay early diagnosis by controlling symptoms and by physiologically increasing gastrin levels. Conversely, however, they may also facilitate timely recognition of Zollinger–Ellison syndrome—if the diarrhea disappears.

The researchers advise treating each patient individually, with careful weighing of benefits and risks, particularly the risk of major bleeding. Their meta-analysis suggests a relative risk reduction of about 10%. They concluded that the expected benefits might not outweigh the risk of major bleeding, particularly among patients at low cardiovascular risk (with a risk of less than 20% over 10 years) or elderly patients (70 years of age and older) with a high risk of bleeding.

Source: Am J Med 2009;122, e9–e10

**New Drugs**

**Questionable Benefits Of Aspirin in Diabetes**

Contrary to current guidelines, aspirin might not be useful in reducing cardiovascular risks in patients with diabetes.

Researchers from Italy and Australia concluded that aspirin might be of less value in diabetic patients than in other high-risk patients. They found no statistically significant reduction in the risk of major cardiac events with aspirin when compared with placebo or no treatment, or a significantly reduced risk of all-cause mortality. Taken together, they say, their data indicate either low efficacy of aspirin in people with diabetes or insufficient evidence of a decreased risk. A subgroup analysis did confirm that aspirin reduced the risk of myocardial infarction (MI) in men by 43% but conferred no benefit in women.

There was no significant reduction in the risk of stroke for men or women, but the researchers noted an opposite trend: the risk of stroke for men or women, but the researchers noted an opposite trend: the risk of myocardial infarction (MI) in men by 43% but conferred no benefit in women.

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Source: BMJ 2009;339:b4531

**Neuropathic Pain After Paclitaxel (Taxol) Therapy for Breast Cancer**

Patients who experience chemotherapy-induced peripheral neuropathy (CIPN) while receiving paclitaxel (Taxol, Bristol-Myers Squibb) are three times more likely to receive a diagnosis of neuropathic pain, according to a study at M.D. Anderson Cancer Center in Texas.

Researchers conducting a survey of 240 patients with breast cancer who had participated in clinical trials of paclitaxel asked the respondents whether they had ever been given a diagnosis of neuropathic pain. Of those, 64% had experienced CIPN during treatment, and 27% of that number had subsequently been told that they had neuropathic pain.

As many as 25% of the respondents reported being under the care of a health care professional for pain. However, patients with neuropathic pain reported twice as many visits to their physicians. Moreover, 50% of these patients had taken prescription medications, compared with 19% of patients who did not have neuropathic pain. Of those patients with neuropathic pain, 63% had taken over-the-counter medications, compared with 45% of patients without neuropathic pain.

The researchers say that diabetes and osteoarthritis were significantly associated with neuropathic pain. Diabetes raised the risk of such pain by five times, and osteoarthritis tripled it.

The cumulative dose of paclitaxel was strongly linked to CIPN. In fact, the cumulative dose was a significant factor throughout the multivariate analysis. At M.D. Anderson Hospital, the researchers say, patients receiving weekly paclitaxel therapy are monitored every four to six weeks for symptoms of worsening CIPN. If the intent of paclitaxel therapy is cure, they add, physicians and patients should discuss the risks and benefits of continuing the current dose of paclitaxel if neuropathy is worsening.

Source: J Pain 2009;11:1146–1150

**IV Lacosamide (Vimpat) Works Well in Emergencies**

Results of two new studies support the use of the intravenous (IV) formulation of lacosamide (Vimpat, UCB), an antiepileptic drug, for patients requiring add-on therapy when oral antiepileptic therapy is temporarily unavailable, such as in emergencies or during surgery.

In one study, lacosamide was generally well tolerated as a replacement for oral therapy in add-on epilepsy therapy. A second study involved a single IV loading dose over a period of 15 minutes, followed by the equivalent daily oral dose given twice daily.

Lacosamide was launched in the U.S. in May 2009 as an adjunctive therapy for the treatment of patients, 17 years of age and older, with partial-onset seizures. The drug’s mechanism of action differs from other antiepileptic agents.

The initial dose should be 50 mg twice daily (100 mg/day). The dose can be increased weekly by 100 mg/day, given as two divided doses, up to the recommended maintenance dose of 200 to 400 mg/day. When the patient is switched from the oral form, the initial total daily IV dosage should be equivalent to the total daily dosage and frequency of the oral form; it should be infused intravenously over a period of 30 to 60 minutes. At the end of the IV treatment period, the patient may be switched to...
oral lacosamide at the equivalent daily dosage and frequency of the IV administration.


Hospitalized Patients Don’t Know Which Drugs They Are Taking

In a study from the University of Colorado in Denver, 44% of hospitalized patients thought they were receiving a drug that they were not, and 96% of these patients could not recall the name of at least one drug that had been prescribed for them during their stay.

In one review, researchers found some degree of error in almost 20% of medication doses. Overall, patients were able to name fewer than half of their hospital medications. Patients had significant deficits in their understanding of their medications even when they thought they knew what was being prescribed to them.

Fifty English-speaking participants between 21 and 89 years of age all stated that they knew what drugs they were taking outside the hospital. Nursing-home residents and patients with a history of dementia were excluded.

Patients younger than 65 years of age were unable to name 60% of the drugs that they could take as needed, whereas patients older than age 65 were unable to name 88% of these medications. This difference remained even after the investigators adjusted for the number of medications. For scheduled agents, there was no difference in recall according to age.

Antibiotics were the most commonly omitted, or not remembered, scheduled medication; 17% of all omitted drugs were from this group, followed by cardiovascular agents (16%) and antithrombotic agents (15%). Among the drugs that could be taken as needed, analgesics (33%) and gastrointestinal agents (29%) were commonly omitted.

The study results suggested that hospitalized patients believe learning about their regimens would increase their satisfaction and might improve medication safety.


FDA Panel Recommendations Rosuvastatin (Crestor) For Preventing Heart Disease

The FDA’s Endocrinologic and Metabolic Drugs Advisory Committee, after weighing benefits and risks, has concurred that there is sufficient benefit to support the use of rosuvastatin calcium (Crestor, AstraZeneca) as a preventive therapy for patients without cardiovascular disease or for those at low risk. The criteria for patients are as follows:

1. Men must be 50 years of age and older, women 60 years of age and older.
2. Levels of fasting low-density lipoprotein-cholesterol (LDL-C) should be below 130 mg/dL.
3. The high-sensitivity C-reactive protein (CRP) level should be 2 mg/L or more.
4. Triglyceride levels should be less than 500 mg/dL.
5. Participants should have no history of cardiovascular or cerebrovascular events, or coronary heart disease risk equivalent, as defined by guidelines of the National Cholesterol Education Program, Adult Treatment Panel III (NCEP ATP III).

The review, based on results of the JUPITER study (Justification for the Use of statins in Prevention: an Intervention Trial Evaluating Rosuvastatin), is part of the FDA’s evaluation of the supplemental New Drug Application (sNDA) that AstraZeneca had filed in April 2009 to update the drug’s prescribing information about its effect on decreasing the risk of cardiovascular events.

Source: AstraZeneca, December 15, 2009

Aztreonam Inhalation Solution For Cystic Fibrosis

The Anti-Infective Drugs Advisory Committee has recommended that aztreonam for inhalation solution (Gilead) be approved for treating infections caused by Pseudomonas aeruginosa in patients with cystic fibrosis. The panel’s vote of 15 to 2 indicated that Gilead has provided sufficient evidence of the safety and efficacy of the product. The panel also voted 17 to 0 that 75 mg three times daily was the correct dose and regimen.

Chronic pulmonary infections resulting from P. aeruginosa are the most common cause of morbidity and mortality among patients with cystic fibrosis.

The FDA has scheduled its review for February 13, 2010. Gilead will continue to make the product available through its expanded access program in the U.S. The company originally submitted its NDA for the potential product in November 2007. In September 2009, the product was granted conditional marketing approval in Canada and Europe as Cayston. Applications for marketing approval of Cayston are also pending in Australia, Switzerland, and Turkey.

Aztreonam has potent in vitro activity against gram-negative bacteria such as P. aeruginosa. When formulated with arginine, aztreonam is approved for IV administration for treating various infections. When formulated with lysine, it is a proprietary formulation developed specifically for inhalation.

This product has been granted orphan drug status in the U.S. and Europe. In the U.S., the FDA has not yet determined that the inhalation solution is safe or efficacious in humans for its intended use.

Source: Gilead Sciences
FDA Opens Branch in Mexico

As part of its efforts to enhance food and medical product safety, the FDA has opened a post in Mexico City. This is the agency’s third post in Latin America and its 10th international post in the past 13 months. In addition to its office in the U.S., the FDA has posts in China, India, Europe, and Latin America.

Source: FDA, December 15, 2009

RECALLS

Cleviprex Emulsion

The Medicines Company is voluntarily recalling 11 lots of clevidipine butyrate injectable emulsion because of the potential presence of visible particulates in some vials.

These lots are affected: 61-978-DW, 61-979-DW, and 61-980-DW (expiration date, January 1, 2010); 68-404-DJ, 68-405-DJ, and 68-406-DJ (expiration date, August 2010); 69-830-DJ, 63-385-DJ, 63-386-DJ, and 63-266-DJ (expiration date, March 2011); and 64-453-DJ (expiration date, April 2011). Unaffected products from lots 68-407-DJ, 68-408-DJ, 71-101-DJ and 71-106-DJ are being shipped to wholesalers and can be ordered by hospitals.

The particulate matter comprises subvisible, inert, stainless steel particles, approximately 2 microns. If these particles were to aggregate or if larger particles were present, however, they could become visible and might reduce blood flow in capillaries, cause damage to tissues, or initiate inflammatory reactions.

Source: FDA, December 16, 2009

Insulin Syringes

Qualitest Pharmaceuticals and the FDA have notified health care professionals of a nationwide recall of all lots of Accusure insulin syringes. The syringes were distributed between January 2002 and October 2009 to wholesale and retail pharmacies nationwide, including Puerto Rico. These syringes may have needles with the potential to detach from the syringe. If the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after injection.

Consumers who have these syringes should stop using them.

Source: FDA, October 27, 2009

Sheath Introducer

The Crossover Sheath Introducer has been recalled because of complaints about stretching or fracture of the sheath during use. The device was developed and manufactured by Thomas Medical Products and was distributed by Cordis. Lots U0000025 through U0000059 are affected.

The long-coil, reinforced, kink-resistant catheter sheath is designed for use in arterial and venous procedures requiring percutaneous introduction of an intravascular device or fluid. If the device fractures, separated segments of the introducer could embolize downstream in the bloodstream and might impede blood flow distal to the point where it lodges, resulting in ischemia or infarction to the distal extremity.

Because the device is coil-reinforced, any separation of the cannula has the potential to expose portions of the coil and could create the potential for vessel dissection or perforation. Open surgery might be necessary to remove the retained segments or to control bleeding.

Source: FDA, October 23, 2009

RESEARCH NEWS

Cancer Studies

Heart Drugs Show Promise In Colon Cancer

A group of medications used to treat heart failure may prove beneficial in fighting colon cancer, according to scientists in Sweden.

Cardiac glycosides are a family of naturally derived drugs that are used to treat congestive heart failure and arrhythmias. Scientists have suspected that these heart drugs might help fight different types of cancer.

As part of a larger study to identify natural substances with activity against colon cancer, the scientists selected several cardiac glycosides for further study. Five of these heart drugs were tested against laboratory cultures of human colon cancer cells. All were found to be effective, to varying degrees, at killing these cancer cells. Sensitivity, however, was low when compared to that of other cancer cell types.

Some of the drugs also showed increased anticancer activity when they were combined with other drugs used for standard chemotherapy. The findings suggest that these heart drugs, when used alone or with chemotherapy agents, may affect colon cancer outcomes.


Gene Position Distinguishes Cancerous from Normal Tissue

Researchers have identified several genes whose position inside the cell nucleus changes in invasive breast cancer tissue compared with normal breast tissue. The findings suggest that these patterns might be used to help differentiate cancerous from normal tissue.

Chromosomes and individual genes occupy certain locations relative to one another within the nucleus. The spatial organization of genes can change during several normal bodily processes, and alterations may also occur in disease states such as cancer. The distinctive changes in shape and size of the cell nucleus, which pathologists use routinely to identify the presence of cancer, suggest that changes in spatial gene organization also occur in the nuclei of cancer cells.

Researchers visualized a set of 20

Vol. 35  No. 1 • January 2010 • P&T 17
genes using fluorescent in situ hybridization (FISH), a technique used to detect specific DNA sequences in intact cells, in a set of 11 normal human breast and 14 invasive cancer tissue specimens. The scientists identified eight genes with a high frequency of repositioning in cancer specimens. Only a minority of tested genes underwent significant repositioning in a given cancer tissue, suggesting that repositioning is gene-specific and does not reflect a large-scale alteration in gene organization. These events did not result from a common cellular occurrence known as genomic instability, which is often associated with cancer, and the repositioning did not correlate with changes in the number of copies of the gene present in the cell.

The scientists next tested whether changes in position could distinguish cancer from normal and non-cancerous tissues. The position of a single gene, HESS, allowed invasive breast cancer tissue to be identified with nearly 100% accuracy. HESS is often associated with cancer. This approach compared favorably with standard diagnostic needle biopsies, although the findings need to be replicated in a set of larger tissue samples.


What Goes Wrong with Cancer Cells?

Scientists at Princeton University have produced a systematic list of the ways a cancerous cell can “go wrong.” The discovery might give researchers a tool that eventually could result in the development of more targeted therapies for patients.

One of the goals of cancer biology is to develop therapies that are more specific than traditional treatments in attacking the pathways that have been co-opted by cancer cells. The challenge is to discover these altered pathways so that they can be restored to their normal state.

The team at Princeton was able to systematically categorize and pinpoint the alterations in cancer pathways to reveal the underlying regulatory code in DNA. They discovered that many components inside the cell can become mutated and give rise to cancer.

The researchers developed an algorithm, a problem-solving computer program, that sorts through the behavior of each of 20,000 genes operating in a tumor cell. Cancer cells often act in aberrant ways, and the algorithm can detect these subtle changes and track all of them.

Pathologists who examine tumors in sick patients analyze a small set of tumor characteristics in order to determine the cells’ diagnostic and prognostic class. The new method could give practitioners an encyclopedic accounting of the alterations in problematic cells and yield more detailed information about the nature of the disease.

The algorithm devised by the group scans the DNA sequence of a given cell (its genome) and deciphers which sequences are controlling what pathways and whether any are acting differently from the norm. By deciphering the patterns, the scientists can conjure up the genetic regulatory code that is underlying a particular cancer.

The scientists developed the technique by using modern methods of systems biology and used powerful computers to sort vast arrays of data. They hope to be able to use this information to design specific therapies for cancer and other diseases—a process that could take many years.

Source: Mol Cell, December 11, 2009

Revlidim Extends Survival In Patients with Multiple Myeloma

Initial results from a large, randomized clinical trial of multiple myeloma (MM) showed that patients who received lenalidomide (Revlidim), Celgene) following a blood stem cell transplantation had less disease progression compared with those who received a placebo. The trial was stopped early because of this response. Sponsored by the National Cancer Institute (NCI), the trial involved patients 18 to 70 years of age.

Autologous blood stem cell transplantation is a procedure in which a patient’s own blood stem cells are removed. The patient is then treated with high doses of chemotherapy, radiation, or both. The blood stem cells are then returned to the patient. This is the first randomized phase 3 trial to show a benefit of lenalidomide following transplant for MM, although evidence of an overall survival benefit was not observed.

Side effects were similar to those observed in other clinical trials with lenalidomide.

A derivative of thalidomide, lenalidomide was approved by the FDA in 2006 for use with dexamethasone, a steroid, for the treatment of MM in patients who had received at least one prior therapy.

MM occurs when a type of immune cell (a plasma cell) crowds out healthy blood cells in the bone marrow, gradually damaging the bones and other organs. Approximately 46,000 people have MM in the U.S.


Genetic Variant May Affect Risk of COPD

Researchers have discovered evidence that suggests a genetic variant may be associated with better preserved lung function among children with asthma and adults who smoke, according to a study funded by the National Heart, Lung, and Blood Institute (NHLBI).

The study also found a link between the genetic variant and a reduced risk of chronic obstructive pulmonary disease (COPD) in adults who smoke. COPD is
The researchers found that a DNA single-nucleotide polymorphism (SNP) helped to preserve lung function among children with asthma and in former or current smokers. The investigators also observed a lower risk for developing COPD in adults who smoke. Adults with this SNP had a 35% reduction in the risk of onset of COPD.

Researchers examined the genes and the breathing capacity of more than 8,300 children and adults from seven different studies, including the NHLBI-funded Childhood Asthma Management Program and National Emphysema Treatment Trial. Using data from all seven studies, researchers found a link between a SNP in MMP12, a gene that encodes matrix metalloproteinase 12, and preserved lung function among both children with asthma and adults who currently or formerly smoked.

The same SNP was also found to be related to a lower risk of COPD. MMP12 is produced by inflammatory cells called macrophages, which are found in the lung.

The study results support the theory that asthma and COPD may share some common mechanisms, even though the two diseases affect patients differently.

Asthma affects more than 22 million people of all ages. COPD affects primarily older individuals and is the fourth leading cause of death in the U.S.


**NEW MEDICAL DEVICES**

**Marvin M. Goldenberg, PhD, RPh, MS**

**Name:** Pathway Articulating Vertebal Interbody Device (AVID)

**Manufacturer:** Custom Spine, Inc., Parsippany, N.J.

**Approval Date:** October 26, 2009

**Purpose:** This body fusion device is designed for use with supplemental spinal fixation systems at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease. Pathway AVID was designed to complement the company’s flagship spinal fixation system. In the articulated position, the large footprint, 35 mm long by 20 mm wide, provides maximum surface area contact to increase stability while reducing the risk of subsidence.

**Description:** Three intralinked spacers are inserted into the disc space via a translaminar approach. After they are inside the disc area, two spacers are sequentially articulated to create an interbody that follows the natural curvature of the vertebra. Autogenous bone graft is used to prepare the device.

**Benefit:** This newly approved spacer may facilitate a quicker recovery for the patient compared with traditional translaminar lumbar interbody fusion spacers. The symmetrical design provides greater load distribution across the vertebral body and allows for the addition of significant amounts of autogenous bone graft to promote bone growth.

**Sources:** www.customspine.com; FDA, www.accessdata.fda.gov

**Name:** 3f Aortic Bioprosthesis

**Manufacturer:** ATS Medical Inc., Minneapolis, Minn.

**Approval Date:** November 2, 2009

**Purpose:** The prosthesis represents a minimally invasive solution for patients with structural heart disease. The ability to remove and replace a diseased heart valve in a noninvasive manner offers an improved clinical and a more cosmetically favorable procedure, compared with the pain and scarring associated with conventional open-chest surgery.

**Description:** Surgeons are recognizing the potential uses of the prosthesis in less invasive port access and robot-assisted procedures. The 3f aortic valve has no rigid supporting stent. As a result, it is completely pliable and can be folded into a small diameter and introduced to the body through small ports. The daVinci Surgical System (Intuitive Surgical) is used in the procedures.

**Benefit:** Robot-assisted, endoscopic aortic replacement gives surgeons and patients another option for the treatment of structural heart disease without an open sternotomy. This method is the result of an ongoing cooperative effort of leading cardiac surgery centers in the U.S. that are experienced in robotic procedures.

**Source:** www.atsmedical.com

**Name:** GuideLiner Catheter

**Manufacturer:** Vascular Solutions, Inc.

**Approval Date:** November 10, 2009

**Purpose:** The catheter provides a coaxial guide extension and rapid exchange for coronary or peripheral interventions. It is available in 6 French (5-in-6), 7 French (6-in-7), and 8 French (7-in-8) sizes. Physicians can use standard-length guide wires, balloons, or stents through an existing hemostatic valve.

**Description:** The GuideLiner catheter is a coaxial “mother-and-child” guide extension with the convenience of rapid exchange that provides backup support and selective deep intubation in complex coronary interventions.

**Benefit:** Deep intubation of the catheter within a soft 6 French guide should provide good backup support and may be less traumatic than using stiff 7 and 8 French guides that were previously required in patients with complex disease. The soft, flexible tip can cross tortuous structures and enables delivery of stents and other equipment directly to the target lesion. The device is as easy to insert as a standard rapid-exchange balloon catheter.

**Source:** www.vascarsolutions.com