January 2012

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Inside This Issue

2011 FDA Investigator Warning Letters

Dec.19.2011

by Mandi Merriott

Choosing the right investigator to conduct a clinical study is the key element in a successful trial. Investigator training during the duration of a clinical study is important in the outcome of the trial not only to the sponsor but also to ensure patient safety is being monitored. In 2011 alone the FDA issued warning letters to 13 clinical investigators conducting clinical trials between 2/16/11 to 11/4/11.

The most significant violations noted from all letters included:

1) **You failed to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60].**

For Protocol (b)(4), Section 5.4.1 specified that the subject was to receive the investigational medication ((b)(4)) once eligibility was confirmed after completion of the screening form and evaluation by the sponsor or its designee. Source records indicate that Subject 214-002102 was dispensed study drug on June 27, 2007, nearly two weeks before you received confirmation of the subject's eligibility for enrollment by the sponsor or its designee on July 9, 2007. You therefore failed to follow the protocol requirements by dispensing investigational medication to a subject prior to confirming the subject's enrollment into the study.

Section 5.3 of the protocol, Adverse Event Reporting Requirements, states, "Adverse events are reported in a routine manner at scheduled times during a trial…." We note that you failed to report the following adverse events to the sponsor in your CRFs for 3 of 3 subjects enrolled... **Read More**

CMS Requires Medicare Pre-Payment Audits for Cardiovascular and Orthopedic Procedures Effective Jan. 1

Dec.14.2011

by Jeffrey D. Zigler, J.D.

The Centers for Medicare & Medicaid Services (CMS) randomly audit health care providers' claims for reimbursement, to recoup funds the program may have already paid under fraudulent or incorrect pretenses, via Recovery Audit Contractors (RACs). This is part of the broad-sweeping Medicare Claim Review Programs established by the government, processes which were formalized in the 1990s. On November 15, CMS announced that Medicare's RACs in certain high-volume or high-population states would begin pre-payment audits of many cardiovascular and orthopedic procedures' claims, prior to releasing payment to providers. This new process, which affects all procedures falling into the below Diagnosis Related Groups (DRGs), will begin on January 1, under the Agency's newest attempt to lower the cost of health care:

Procedures in Orthopedic DRGs

- 458-Spinal fusion except cervical w/spinal curve, malign, or 9+ fusions w/o CC
- 460-Spinal fusion except cervical w/o MCC
- 470-Major joint replacement or reattachment of lower extremity w/o MCC
- 490-Back and neck procedures except spinal fusion w/CC/MCC or disc device/neurostimulator

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Risk Aversion — The Benefits of a Corporate Surgeon Presentation Review

Dec.9.2011

by Amanda Briscoe Tracy, MS

It is no secret that today's wary industry is driving key decision makers to continuously evaluate internal corporate risk aversion strategies to better their corporate infrastructure.

We all have recognized increased industry scrutiny, as evidenced by the recent prison sentences of former Synthes executives.

As such, it is now imperative that medical device companies, large and small, take appropriate measures and precautions to eliminate risks of off label promotion of their products to surgeons.

The most effective way to secure risk aversion is to have an independent/non-biased assessment performed on your Company's surgeon presentation process. A surgeon presentation process review should take into account the risks involved on multiple levels, ie- regulatory, reimbursement, clinical, intellectual property and compliance perspectives. Potential risks, concerns, or possible deficiencies should be the primary objective of the review and case specific guidance on recommended corrective action should also be provided. **Read More**

It's That Time of Year: Annual Establishment Registration!

Dec.8.2011

by Michelle McDonough, MS

It is time to complete your annual establishment registration if you have not already done so. Medical device facilities should complete the registration process for 2012 between October 1 and December 31, 2011. The registration fee for fiscal year 2012 is $2,029 for all establishments including small businesses. Access to the FDA electronic registration and listing database can be found here.

Figuring out when to register and when to list can be confusing, however; a detailed list of all establishment types that have to pay the registration fee can be found at "Who Must Register, List, and Pay the Fee". The FDA also provides contact information for assistance (be prepared to leave a message and wait 1-5 days for a response):
Phone: 301-796-7400
Email: reglist@cdrh.fda.gov

Commonly listed establishments include:

- Manufacturer: Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" according to FDA.
- Specifications Developer: Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing. Manufacturing is typically carried out by a contract manufacturer.
- Contract Manufacturer: Manufactures a finished device to another establishment's specifications.
- Contract Sterilizer: Provides a sterilization service for another establishment's devices. **Read More**

CMS Issues 2012 Final Rules: Physician Fee Schedule and Hospital Outpatient Prospective Payment System

Nov.30.2011

by Daria Harlin, J.D.

Earlier this month, the Center for Medicare and Medicaid Services (CMS) issued two final rules for 2012, addressing modifications to the payment policies under Medicare's Physician Fee Schedule (PFS) and updates to payments policies and payment rates furnished in hospital outpatient departments and ambulatory surgical centers. Both final rules address comments and concerns submitted in response to the respective CY 2012 proposed rules issued earlier this year, and both contain modifications and updates that are extremely relevant to physicians and to other key stakeholders within the orthopedic and medical device industry.

Under the 2012 Hospital Outpatient Prospective Payment System, Medicare payments will increase by 1.9 percent to hospital outpatient departments (HOPDs) and 1.6 percent to ambulatory surgery centers (ASCs), beginning on January 1, 2012. CMS also evaluated the "inpatient-only" list and removed several cervical arthrodesis and spine allograft codes from this list for 2012. These procedures (CPT 22551, CPT 22554, CPT 20930 and CPT 20931) are now payable by Medicare in the outpatient setting of care. **Read More**

Rapid Growth in Medical Device Patents Means Expert Searchers Are Essential

Nov.18.2011

by Andy Riutta

Searching is a critical element of successful intellectual property (IP) development and management. For patents, searching can provide strategic information regarding new opportunities for patenting your ideas or technologies as well as potential risks for infringement presented by your competitors' patent portfolios. Table I (click on it to see the full size) describes common types of patent searches.

Table I: Patent Search Types

Type	Purpose	When Commonly Performed
Clearance Freedom-to-Operate	Helps to minimize your risk of infringing the patients of your competitors by bringing to light patents with claims that could block you from making, using or selling a given product or technology.	» Key elements of product or technology are conceptually established. » Before purchase of rights to product or technology.
Competitive Patent Landscape	Compiles collection of patent references relevant to a given product or technology so that you can see the relationship of the product or technology to the rest of the field.	» Early in new product or technology development stage. » During re-design or next generation design of a product.

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Open Comment Period for Orthopedic Stem Cell Medical Coverage Policy Ends Soon

Nov.14.2011

by Timothy Hunter

Blue Cross Blue Shield of Alabama currently is accepting public comments for a draft medical coverage policy pertaining to orthopedic stem cell uses (Policy #430: Orthopedic Applications of Stem Cell Therapy). The full draft policy can be reviewed here (pdf).

In the draft policy, Blue Cross Blue Shield of Alabama denies coverage access for mesenchymal stem cell (MSC) therapies for orthopedic uses. According to the health plan, the primary reason for non-coverage is the lack of sufficient evidence for autologous techniques and the lack of clinical study results for drug and biologic products currently in development.

Mesenchymal stem cell therapy for all orthopedic applications, including use in repair or regeneration of musculoskeletal tissue, does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered investigational.

While the draft non-coverage determination is expected for technologies currently in clinical study, stakeholders for autologous MSC uses may wish to submit a comment to Blue Cross Blue Shield to ensure that the health plan is appropriately evaluating the full body of published evidence. The deadline for comment submission is November 21, 2011. Commenters can submit a feedback form electronically or submit formal comments by mail or fax. Full directions for comment submission can be found here.

CMS/FDA Announce Parallel Review Pilot Program

Nov.2.2011

by Daria Harlin, J.D.

In the September 17, 2010 issue of the Federal Register, the Center for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) announced their intent to initiate a process for parallel evaluations of FDA-regulated medical products whereby FDA's premarket review and CMS's national coverage determination process would occur simultaneously. This parallel review will not change the existing separate and distinct review standards for FDA device approval and CMS coverage determination, but will simply streamline the process. The September 2010 announcement, which invited public comment on the issue, also announced the plan to establish a voluntary pilot program for this parallel review.

Earlier this month, and following the December deadline for comment submission, the agencies issued notice of the procedures for participation in the voluntary pilot program. CMS and the FDA reiterated that parallel review will reduce the time between FDA marketing approval and CMS national coverage determination (NCDs). According to the Agencies, this efficiency will benefit both patients and sponsors. Medicare beneficiaries will be advantaged by earlier access to these pioneering medical products, while sponsors will benefit from accounting for both CMS and FDA questions at the inception of the study. No longer will sponsors be placed in a position where the clinical study satisfies FDA requirements for premarket approval, but fails to address coverage issues that are raised further down the line and that may ultimately block patient access to the product(s). **Read More**

Overview of Coding Development and Authority

Nov.1.2011

by Daria Harlin, J.D.

Most professionals within the healthcare industry possess at least some familiarity with the Current Procedural Terminology (CPT) coding system and the ways in which these codes facilitate communication between payors, providers and physicians. Despite varying levels of facility with specific coding methods, many industry professionals are nevertheless unaware of the detailed and in-depth process for the modification, addition or deletion of a code.

The CPT is a numeric coding system maintained and updated by the American Medical Association (AMA). First published in 1966, the CPT has helped standardize descriptors used to document medical procedures, services and instrumentation. It provides a uniform and accurate language for reporting medical procedures and diagnoses, and is additionally used for billing purposes. In 1983, the Center for Medicare and Medicaid Services (CMS) adopted the CPT as part of their own coding system, the Healthcare Common Procedure Coding System.

Very specific procedures have been put into place by the AMA for revising, adding or deleting codes. Decisions as to the addition, deletion, or revision of codes are made by the 17-member CPT Editorial Panel, which has been authorized by the AMA to maintain the CPT code set. The CPT Editorial Panel is also supported by the CPT Advisory Committee, a larger body of advisors comprised mostly of physicians who provide supplemental counsel and expertise to the Editorial Panel. **Read More**

Why did FDA Request §522 Postmarket Studies and What Will They Tell Us?

Oct.27.2011

by Justin Eggleton

The last two years have seen FDA issue §522 postmarket study requests for several orthopedic device types. These devices include pedicle screw systems intended to stabilize the spine during the fusion process and metal-on-metal hip replacements. Metal-on-metal hip replacements have also come under scrutiny following higher than expected failure rates in a British registry.

While the metal-on-metal hip replacements have received considerable media coverage, some may wonder why pedicle screw systems have not experienced similar scrutiny. Why did FDA issue requests for postmarket studies on 16 pedicle screw systems to begin with?

FDA cleared the Zimmer Dynesys Spinal System in 2004, which differs from traditional pedicle screw systems due to its more compliant design. Subsequent to this clearance, a number of compliant pedicle screw systems were cleared leveraging Dynesys as a predicate until early 2008, when FDA started to receive MDRs related to these more compliant devices.

One particular system required a class 2 recall due to shear failure of the internal cable, which was a failure mode not observed in pre-clinical testing. Consequently, FDA took the position pre-clinical testing does not sufficiently predict clinical performance. Once the recall was initiated in September 2008 and MDRs were reported for other systems, the FDA shift in review policy was two-fold. **Read More**

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OIG Work Plan 2012 Adds Investigation of PODs

Oct.10.2011

by Christopher Gingras, FACHE CFE FHFMA

As expected based on a recent report to the Senate by the OIG, the investigation of physician-owned distributors of spinal implants (PODs) has been added to the 2012 OIG Work Plan.

This could significantly alter the competitive landscape and may bring clarity to a complex issue. The investigation could mean the end of PODs or it might identify some physician distributorship models which are more acceptable than others.

Here's the excerpt from the Work Plan:

Physician-Owned Distributors of Spinal Implants (New)

We will determine the extent to which physician-owned distributors (POD) provide spinal implants purchased by hospitals. We will also analyze Medicare claims data to determine whether PODs we identify in our review are associated with high use of spinal implants. PODs are business arrangements involving physician ownership of medical device companies and distributorships. PODs are focused primarily in the surgical arena and currently primarily involve orthopedic implants such as spine and total joints. However, PODs appear to be quickly growing into other areas such as cardiac implants. Congress has expressed concern that PODs could create conflicts of interest and safety concerns for patients. (OEI; 01-11-00660; expected issue date: FY 2012; work in progress).

South Korea Fines Pharmaceutical Companies. Could You Be Next?

Oct.7.2011

by Christopher Gingras, FACHE CFE FHFMA

Earlier this month South Korea sent a shot across the bow of six pharmaceutical companies which should make medical device companies with international operations stand up and take notice. Those found guilty included Bayer, Astra Zeneca, Novartis and Sanofi Aventis.

While the fines were not significant the message was quite clear, improper inducements are no longer acceptable. What did these companies do that was so wrong? The usual suspects of golf outings, consultancy fees, free dinners and cash in the form of "post market surveillance studies" were all specifically mentioned.

Increasing Foreign Corrupt Practices Act (FCPA) enforcement, enactment of the UK Bribery Act and actions such as those taken by South Korea should make it abundantly clear that the same old way of doing business will result in reputational damage, significant fines, governmental investigation and possibly your picture on the front page of the paper.

Three Step Prevention Process

So how do you, as a medical device company, avoid this fate?

The first step is to clearly document in writing what is acceptable and not acceptable in terms of behavior. Many organizations already have an FCPA policy but those will need to be revised as the FCPA focuses on governmental representatives but the UK Bribery Act addresses the impropriety of bribery in general. It is easier to tell employees that bribery is not appropriate instead of having a policy for the FCPA and one for the UK Bribery Act. Why make it complicated and confusing?

In addition to the Code of Conduct, contracts and your external website should all reference your anti-bribery initiatives. These materials may need to be in other languages.

After having clear, easily understandable guidelines you need to train, train and train your employees or representatives. The training should include examples applicable to your business and a test so that you can document employee comprehension of the materials. After the initial training, periodic reminders and an annual refresher are necessary. **Read More**

Possible Changes Coming to Spine Procedures Coding and Bundling

Oct.6.2011

by Carolyn Neumann

While attending the recent Advanced Orthopedic Coding, Billing & Reimbursement Symposium, MCRA's professional coding consultants noted a clear trend by the American Medical Association (AMA) and it's Relative Value Scale Update committee (RUC) toward bundling of spine surgery codes, to include more and more procedures into existing AMA Current Procedural Terminology (CPT) codes.

While this may increase efficiencies in coding and billing, overall reimbursement may be affected. In 2011, the AMA issued new CPT codes to the orthopedic industry which bundled many procedures that are commonly performed together during cervical arthrodesis and in 2012 newly revised codes will most likely offer more bundled spine procedures in other scenarios.

A notable surgeon, Dr. Gregory Przybylski, presented a pre-conference compendium and spine coding Q&A session. His presentation on bundling of procedures confirmed that the trend will only continue. **Read More**

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Top Orthopedic Roundup Today News Articles during Q3, 2011

Clinical, Regulatory, IP, Compliance, Reimbursement

1. Smith & Nephew $85 Million Verdict Against Arthrex Removed
2. Exactech Initiates Multi-Center Clinical Trial for New Cartilage Regeneration Technology
3. Amp Orthopedics Expands Clinical Pipeline Initiating Two Trials For Post-Surgical Indications: Knee Replacement and Rotator Cuff Repair
4. Bill Would Require More Monitoring of Implants
5. Affordable Care Act Sunshine Rule Increases Transparency In Health Care
6. TranS1 Inc. Announces Reimbursement Coverage Decision RegardingAxiaLIF(R) Procedure
7. DePuy Orthopaedics Receives FDA PMA Approval For New AOX™ Antioxidant Polyethylene
8. Medtronic Infuse Woes Prompt Subpoena from California Attorney General
9. CMS Tightening the Screws on Unnecessary Procedures in Florida and 10 Other States
10. Stryker sues DePuy, Wright and Zimmer over hip implant patent
11. Life Spine Awarded Seven New Patents, Launches Six New Product Lines & Realizes 25% Sales Growth
12. California-Based DFine Inc. to Pay U.S. More Than $2.3 Million to Settle Claims That Company Paid Kickbacks to Physicians
13. Feds subpoena TranS1 in fraud probe
14. Obama Administration's regulatory reductions to save health care system nearly $1.1 billion
15. FDA-CMS Parallel Review

Finance, M&A & Other Corporate Transactions

1. Radius Health takes final bite of its $91M financing apple
2. Anika Therapeutics Announces U.S. MONOVISC® License and Supply
3. Agreement with DePuy Mitek, Inc.
4. Switzerland's Synthes investors vote to accept J&J's $21.3 billion acquisition offer
5. Baxter Signs Definitive Agreement to Acquire Synovis
6. Symmetry Medical to Acquire the Surgical Instruments Business of Codman & Shurtleff
7. Stryker Announces Additional $500 Million Share Repurchase Program and Declares 18% Increase in Quarterly Dividend
8. Small Bone Innovations, Inc. Secures $43 Million Credit Facility
9. Memphis-based ExtraOrtho is acquired by Zimmer Holdings of Warsaw, Indiana
10. aap generates EUR 21.0 million in nine-month sales and EUR 2.9 million in EBITDA – a 23% adjusted EBITDA increase
11. Zimmer Announces Acquisition of XtraFix® External Fixation System
12. DFINE, Inc. Announces Close of $25 Million Financing
13. Pivot Medical Raises $32 Million in Series C Financing
14. EU Commission Opens In-Depth Probe Into Johnson & Johnson's Synthes Buy
15. Zimmer Spine and Benvenue Medical Enter Exclusive Distribution Agreement for Kiva® VCF Treatment System
16. Israeli back pain device company lands $3.5M investment, plans Akron move

Technology, Product & Industry

1. Zimmer Introduces New CLS® Brevius™ Hip Stem with Kinectiv® Technology in the United States
2. Exactech Continues to Expand Spine Portfolio with Comprehensive Solution to Posterior Cervical Fusion
3. Pitt adopts Orthotag's NFC-enabled orthopedic tag solution
4. 3-D Printer Used to Make Bone-Like Material
5. Arthrosurface Crosses the 30,000 Patient and 100 Publication Milestones
6. Medtronic Introduces New Procedure for Minimally Invasive Spinal Fusion
7. Integra LifeSciences Grows Its Presence in the Spinal Deformity Market
8. FzioMed Announces 250,000 Units of Oxiplex Sold
9. K2M Continues its Momentum with Nine New Products at 2011 North American Spine Society Annual Meeting
10. Arthrosurface Launches World's First Talus Resurfacing Implant for the Ankle
11. MEDICREA INTERNATIONAL: EUROSPINE 2011: Launch of Six New Products
12. HipSextant™ Navigation System Receives Its First Commercial Use
13. Biomet Celebrates 35 Years of Clinical Experience With the Oxford® Partial Knee System
14. Mazor sells 2 robotic systems for $1.4m
15. Integra LifeSciences Meets Surgeon Demand for User-Friendly Minimally Invasive Spinal Solutions

Operational, HR & Other

1. Integra LifeSciences Announces Appointment of Peter Arduini as President and Chief Executive Officer; Stuart Essig Named Chairman of the Board
2. Ex-Synthes Executive Gets Eight-Month Term in Bone-Cement Case
3. LDR Opens New and Expanded Global Headquarters in Austin, Texas
4. MAKO Surgical Corp. expands, boosts jobs
5. DJO Global Announces Departure of Chief Operating Officer
6. Zimmer to Open New Chinese Facility
7. Integra LifeSciences Establishes First Office in Shanghai, China
8. Orsinger alights with $52M golden parachute from Synthes sale
9. Malaysia Strengthens Position as Scientific Engineering Products Supplier In Germany
10. Ivivi Orthopedic Health Announces Name Change to Amp Orthopedics
11. Medtronic CEO sees no edge in spin-off
12. Baxano Rapidly Expands Sales Force to Support Robust Demand for the iO-Flex® System
13. VCs align with med-tech makers to lobby for change in FDA review process
14. Olympus shares plunge after president is sacked
15. Synthes shareholders to Vote Dec. 15 on J&J Deal

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Search the 510(k) Premarket Notification Database for more information on the below clearances

Q3-2011 Orthopedic Panel 510(k) Clearances

Joint

Device Name	Applicant	510(k) #	Decision Date
IFS Subtalar Implant	Internal Fixation Systems, Inc.	K113399	12/20/11
Limacorporate Smr Reverse Shoulder Syste	Limacorporate S.P.A.	K113523	12/20/11
Healix Knotless Anchor	Depuy Mitek, A Johnson & Johnson Company	K113534	12/20/11
Comprehensive Reverse Shoulder	Biomet Manufacturing, Inc.	K113121	12/16/11
Msa Hip System	Global Manufacturing Technology	K113107	12/15/11
Rog Suture Anchor	Rog Sports Medicine, Inc.	K113299	12/15/11
Comprehensive Segmental Revision System	Biomet, Inc.	K111746	12/15/11
Cufflink(Tm) Knotless Anchor With Insert	Cayenne Medical, Inc.	K112876	12/15/11
Conformis Itotal Cruciate Retaining (Cr)	Conformis, Inc.	K112780	12/15/11
Osteospring Footjack Subtalar Implant Sy	Osteospring Medical, Inc	K112658	12/12/11
Spacer-S	Tecres Spa	K112983	12/12/11
Evolution Mp Adaptive Cs Insert	Wright Medical Technology, Inc.	K113325	12/9/11
Exactech Equinoxe Cage Glenoids	Exactech, Inc.	K113309	12/8/11
Disco Subtalar Implant	Trilliant Surgical Ltd	K111834	12/6/11
Apex Modular Acctabular Cup (Now Named A	Omnlife Science	K112779	12/2/11
Profemur Gladiator Ha Hip Stem	Wright Medical Technology, Inc.	K112150	11/23/11
Rsp Glenoid Baseplate Porous Coated	Encore Medical, L.P.	K112069	11/15/11
Profemur Xm Wingless Distal Centralizer,	Wright Medical Technology, Inc.	K113019	11/10/11
Knotless Suture Fixation System	Core Essence Orthopaedics	K111716	11/10/11
Humelock Cemented Shoulder Prosthesis	Fx Solutions	K111097	11/9/11
Ascension Nugrip Cmc Implant	Ascension Orthopedic	K112278	11/4/11
Milestone Knee System, Femoral Component	Tgm Medical, Inc.	K112285	11/4/11
Aequalis Shoulder System	Tornier	K111902	11/3/11

Joint

Device Name	Applicant	510(k) #	Decision Date
Nano Suture Anchor	Linvatec Corporation D/B/A Conmed Linvat	K112965	11/2/11
Duocentric Reversed	Aston Medical	K103251	10/28/11
Healix Knotless(Tm) Anchor	Depuy Mitek, A Johnson & Johnson Company	K112249	10/25/11
Polarcup Dual Mobility System	Smith & Nephew, Inc.	K110135	10/14/11
Gladiator Hip Stem	Wright Medical Technology, Inc.	K111910	10/14/11
Bencox Id Stem, Bencox Metal Head, Benco	Corentec Co., Ltd	K112019	10/12/11
Aequalis Ascend Modular Reverse Shoulder	Tornier, Inc.	K112615	10/11/11
Cls Brevius Stem With Kinectiv Technolog	Zimmer Gmbh	K110836	10/7/11
Mectacer Biolox(R) Delta Femoral Heads	Medacta International	K112115	10/7/11
Exeter X3 Rimfit Acetabular Cup	Stryker Corp.	K111848	10/5/11
Reverse Shoulder Prosthesis Monoblock He	Encore Medical, L.P.	K111735	10/3/11

Spine

Device Name	Applicant	510(k) #	Decision Date
Lanx Posterior Cervicothoracic Spinal Fi	Lanx, Inc.	K113434	12/19/11
Medacta-C	Medacta International	K112862	12/19/11
Instinct Java System	Zimmer Spine	K113270	12/16/11
Lanx Cervical Sa	Lanx, Inc	K112388	12/16/11
Lancer Pedicle Screw System	Spinal Solutions, Llc	K110633	12/15/11
4-Web Alif Spinal Truss System (Sts)	4-Web, Inc.	K112316	12/14/11
Staxx(R) Xd System	Spine Wave, Inc.	K111418	12/13/11
Vbb System	Synthes	K110604	12/13/11
Cougar System	Johnson & Johnson	K113348	12/13/11
Synthes Zero-P	Synthes Spine Co.Lp	K112459	12/12/11
Acculif Tl Cage	Coalign Innovations, Inc.	K113465	12/12/11
Xingtm Spine System	Implanova Co. Ltd	K111995	12/12/11
Genesys Spine Anterior Cervical Plate Sy	Genesys Spine	K111132	12/9/11
Zavation Cervical Plate System	Zavation Llc	K112533	12/8/11
Varilift Cervical Interbody Fusion Syste	Wenzel Spine	K111123	12/8/11
Shield Kyphoplasty System	Soteira, Inc.	K093477	12/8/11

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Spine

Device Name	Applicant	510(k) #	Decision Date
Athena Pedicle Screw System	Royal Oak Medical Devices	K110046	12/7/11
Spartan S3 Facet System	Amendia, Inc.	K113011	12/6/11
Bendini(Tm) Spinal Rod Bending System	Nuvasive, Inc.	K111811	12/5/11
Axle Peek Interspinous Fusion System	X-Spine Systems, Inc	K112592	12/5/11
Acculif Tl-Peek Ibf Cage	Coalign Innovations, Inc.	K112095	12/1/11
Alamo C	Alliance Partners, Llc	K112361	11/30/11
Rhausler Plage Anterior Cervical Fusion	Rhausler, Inc.	K111272	11/29/11
Raptor Facet Fixation System	Alphatec Spine, Inc.	K110170	11/28/11
Trabecular Metal (Tm) Fusion Device	Zimmer Spine, Inc	K111119	11/23/11
Zavation Spinal System	Zavation Llc	K112484	11/22/11
Devine Spinal System	Changzhou Orthmed Medical Instrument Co.	K111690	11/22/11
Cd Horizon Spinal System	Medtronic Sofamor Danek Usa, Inc.	K113174	11/21/11
Clydesdales Spinal System	Medtronic Sofamor Danek Usa, Inc.	K112405	11/21/11
S4 Spinal System	Aesculap Implant System, Inc.	K112551	11/21/11
Depuy Pulse Anterior Cerical Plate Syste	Medos International Sarl	K112724	11/21/11
Pass Lp Spinal System	Medicrea International	K112493	11/21/11
Gibralt Spine Systems Facet Screw 04.0,0	Exactech, Inc.	K112097	11/21/11
Guardian Inflatable Bone Expander System	Bm Korea Co., Ltd.	K111593	11/18/11
Vista-S Device Model 08/06-401-Xxxxx, 08	Zimmer Trabecular Metal Technology	K111983	11/18/11
Synthes Uss Connectors	Synthes Spine	K111358	11/18/11
Sterispineps Pedicle Screw	Safe Orthopaedics	K112453	11/15/11
Anatomic Peek Cervical Fusion System	Medtronic Sofamor Danck Usa, Inc.	K112444	11/15/11
Nanovis Intervertebral Body Fusion Syste	Nanovis, Llc	K110442	11/9/11
Telamon Peek Spinal System	Medtronic Sofamor Danek Usa	K110562	11/9/11
Calix Pc Spinal Implant System	X-Spine Systems, Inc	K112036	11/8/11
Prow Fusion	Nlt Spine Ltd	K112359	11/8/11
Synthes Zero-P Variable Angle (Va)	Synthes Spine Co.Lp	K112068	11/7/11

Spine

Device Name	Applicant	510(k) #	Decision Date
Leucadia(Tm) Mis Pedicle Screw System	Phygen, Llc	K112931	11/2/11
Mahe Perfect Spine-Pedicle Screw System	Mahe Medical Gmbh	K110655	10/27/11
Invizia Anterior Cervical Plate System	Zimmer Spine, Inc.	K111796	10/27/11
Synthes Sternal Fixation System	Synthes Inc	K112689	10/26/11
Expedium Spine System	Johnson & Johnson	K110551	10/26/11
Bonebac T-Plif Intervertebral Body Fusio	Thompson Mis Inc	K111512	10/26/11
Vusion(R) Os	Ortho Development	K111965	10/25/11
Affirm (Tm) Vcf System	Algea Therapies	K110998	10/25/11
Venus Interbody Fixation System- Venus P	L & K Biomed Co., Ltd	K110783	10/24/11
Enspire Debrider System	Spine View, Inc.	K110992	10/21/11
Cd Horizon Spinal System	Medtronic Sofamor Danek, Inc.	K112473	10/21/11
Synthes Xrl	Synthes Spine Co.Lp	K103320	10/20/11
Xtrafix External Fixation System	Extraortho Inc	K111155	10/20/11
Smartloc Spinal Fixation System	A-Spine Asia, Co., Ltd	K111883	10/18/11
Apclo Pedicle Screw Systems	Atlas Spine Inc.	K112759	10/18/11
Gs Medical Anyplus Peek Lumbar Cages (Al	Gs Medical Co., Ltd.	K111354	10/17/11
Zyston Straight Spacer System	Biomet Spine	K112014	10/17/11
Sfc Vertebral Body Replacement	Konigsee Implantate Gmbh	K110153	10/12/11
Cornerstone (R) Psr Cervical Fusion Syst	Medtronic Sofamor Danek Usa	K111264	10/12/11
Concorde Bullet Spinal System	Johnson & Johnson	K110694	10/11/11
Fortify(Tm) And Fortify(Tm)-R Corpectomy	Globus Medical, Inc.	K112756	10/7/11
Range Spinal System (Mesa And Denali)	K2m, Inc.	K112037	10/6/11
Sovereign Spinal System	Medtronic Sofamor Danek, Inc.	K110063	10/4/11
Idr spine cervical interbody fusion syst	Idr spine usa inc.	K113559	12/29/11
arts2 spinal fixation system	advanced medical technologies	K103573	12/28/11
zavation ibf systems	zavation llc	K112664	12/23/11
range spinal system (mesa and denali)	k2m, inc.	K112920	12/21/11
synthes mirs	synthes spine	K113044	12/21/11

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Trauma

Device Name	Applicant	510(k) #	Decision Date
Axsos locking plate system	Stryker corp.	K112926	12/19/11
Zimmer plates and screws system screws o	Zimmer, inc.	K112885	12/19/11
Reconstruction locking plate and 3.5Mm l	Xiamen double engline medical material c	K112819	12/16/11
Prophecy inbone pre-operative navigation	Wright medical technology, inc.	K110360	12/16/11
Arthrex biocomposite transfix	Arthrex, inc.	K112040	12/15/11
Aptus(r) distal humerus system	Medartis ag	K112560	12/15/11
Ace-fischer(r), tempfix(r), hoffman clas	Depuy orthopaedics, inc.	K112218	12/15/11
Headless compression screw	Skeletal dynamics, llc	K112672	12/13/11
Interface bone void filler	Biostructures, llc	K112857	12/13/11
Ortholoc 3dsi locking screws	Wright medical technology, inc.	K113339	12/12/11
Arrow-lok digital system	Arrowhead medical device technologies ll	K112675	12/12/11
Renovis cannulated screw system	Renovis surgical technologies, llc	K113084	12/9/11
Si-lok sacroiliac joint fixation system	Globus medical, inc.	K112028	12/9/11
Osleobridge idsf spacer conector	Merete medical gmbh	K113303	12/9/11
Modified rog suture anchor	Rog sports medicine, inc.	K112991	12/8/11
Ascension atlas humeral plating system	Ascension orthopedics, inc.	K110700	12/6/11
Synthes cortical screws	Synthes (usa) products llc	K112583	12/5/11
Lateral button	T.A.G. Medical products corporation, ltd	K112296	12/1/11
Biomet microfixation sternal closure sys	Biomet microfixation, inc.	K111908	11/29/11
Synthes brainlab trauma compatible instr	Synthes (usa) products llc	K111891	11/28/11
Nb3d bone void filler	Pioneer surgical technology, inc.	K111944	11/22/11
Synthes lcp pedintric plate systems	Synthes (usa) products llc	K112085	11/17/11
Memometal intra-medullary bone fastener	Memometal technologies	K112197	11/17/11

Trauma

Device Name	Applicant	510(k) #	Decision Date
Acu-sinch repair system and acumed sutur	Acumed llc	K112111	11/14/11
Peri-loc proximal femur locking bone pla	Smith & nephew, inc.	K112406	11/14/11
Fuze: intramedullary internal fixation n	Vilex, inc.	K102413	11/14/11
Trimed clavicle fixation system	Trimed, inc.	K112509	11/4/11
Dyna-extor ii	Bk meditech co., Ltd.	K110426	11/2/11
Distal volar radius plating systems	Medos international sarl	K112345	10/31/11
Ncb periprosthetic femur polyaxial locki	Zimmer, inc.	K112174	10/26/11
Framewalker	Quantum medical concepts, llc.	K111993	10/24/11
Mediscope compressiopn staple and access	Mediscope manufacturing, inc.	K102387	10/24/11
Lateral superior clavicle plate, left an	Advanced orthopaedic solutions, inc.	K103513	10/24/11
Tiger headless cannulated screws	Trilliant surgical ltd	K112737	10/20/11
Novabne putty bioactive synthetic bone g	Novabone products, llc	K112773	10/14/11
Mtf new bone void filler	Musculoskeletal transplant foundation	K110003	10/13/11
Apex kirschner wires and steinmann pins	Apex tools & orthopedics co.	K112254	10/11/11
Smith & nephew cannulated screws and was	Smith & nephew, inc.	K111994	10/11/11
Osteomed hand fusion system	Osteomed l.P.	K111419	10/7/11
Ortholoc(tm) bone screws	Wright medical technology, inc.	K112772	10/7/11
Easylock osteosystem	Trimed, inc.	K111266	10/6/11
Zimmer periarticular screws	Zimmer inc.	K111447	10/5/11
suspension clavicle fracture fixation sy	suspension orthopaedic solutions, llc	K112923	12/27/11
stryker resorbable fixation system	stryker	K113109	12/23/11
cols peek	fournitures hospitalieres industrie	K113591	12/22/11
arthrex fracture system	arthrex, inc.	K112437	12/21/11

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Other			
Device Name	**Applicant**	**510(k) #**	**Decision Date**
Medisiss Reprocessed Arthroscopic Shaver	Medisiss	K113028	12/20/11
Synthes Suprapatellar Insertion Instrume	Synthes (Usa)	K111667	12/5/11
Acufex Director Application Anatomic Gui	Smith & Nephew Inc., Endoscopy Div.	K111843	11/14/11
Dash Hip	Brainlab, Ag	K110021	10/18/11
Prophecy Pre-Operative Navigation Alignm	Wright Medical Technology, Inc.	K103598	10/17/11
Zimmer Patient Specific Instruments Plan	Materialise N.V.	K111492	10/13/11
confidence high viscosity spinal cement,	medos international sarl	K112907	12/22/11

Search the Premarket Approval (PMA) Database for more information on the below approvals

Q3 2011 - Orthopedic Advisory Premarket Approval (PMA)

Joint			
Device Name	**Applicant**	**510(k) #**	**Decision Date**
Lcs Total Knee System	Depuy Orthopaedics,	P830055 S106	11/23/11
Cormet Hip Resurfacing Sy	Corin U.S.A.	P050016 S008	11/10/11
Trilogy Ab Acetabular Sys	Zimmer, Inc.	P040048 S015	11/4/11
Pinnacle Complete Acetabu	Depuy Orthopaedics,	P090002 S001	11/4/11
Reflection Ceramic Acetab	Smith & Nephew, Inc.	P030022 S017	10/14/11
Birmingham Hip Resurfacin	Smith & Nephew, Inc.	P040033 S017	10/14/11
Euflexxa (1% Sodium Hyalu	Ferring Pharmaceutic	P010029 S008	10/11/11
Synvisc And Synvisc-One	Genzyme Corporation	P940015 S022	10/7/11
Synvisc & Synvisc-One (Hy	Genzyme Corporation	P940015 S023	10/7/11
NEXGEN COMPLETE KNEE SOLU	zimmer, inc.	P060037 S015	12/23/11
ZIMMER NEXGEN LPS-FLEX MO	zimmer, inc.	P060037 S014	12/21/11
DURALOC OPTION CERAMIC HI	depuy orthopaedics,	P040023 S019	12/20/11

Spine			
Device Name	**Applicant**	**510(k) #**	**Decision Date**
Cervical-Stim	Orthofix, Inc.	P030034 S006	11/2/11
Physio-Stim & Spinal-Stim	Orthofix, Inc.	P850007 S032	11/2/11
Infuse Bone Graft/Lt-Cage	Medtronic Sofamor Da	P000058 S046	10/5/11
Prodisc -L Total Disc Rep	Synthes Spine	P050010 S009	10/4/11
INFUSE BONE GRAFT/LT-CAGE	medtronic sofamor da	P000058 S045	12/23/11
PRODISC -C TOTAL DISC REP	synthes spine	P070001 S010	12/22/11

Other			
Device Name	**Applicant**	**510(k) #**	**Decision Date**
ORTHOVISC HIGH MOLECULAR	anika therapeutics,	P030019 S014	12/30/11

About MCRA, LLC

MCRA was founded in 2004 and is the leading neuro-musculoskeletal consulting firm assisting companies at all stages of development, whether they are single-product companies or companies with several thousand technologies. MCRA provides "first-in-class" service to its clients through its superior knowledge base, global surgeon relationships and deeply experienced management team. The true value of MCRA is the integration of six business value creators—regulatory, reimbursement, clinical, intellectual property, quality assurance and healthcare compliance. MCRA's integration of these key value creating initiatives, as well as its focused specialization, creates unparalleled expertise to its clientele. For more information on MCRA please visit www.mcra.com.