



Orthopedic Intelligence

Specializing in the Neuro-Musculoskeletal Industry

Clinical • Regulatory • Reimbursement • Quality Assurance • Intellectual Property • Healthcare Compliance

INSIDE THIS ISSUE

Orthopedic Intelligence Posts 1-2

Patient Protection and Affordable Care Act: An Effort to Lower Cost and Reduce Waste	1
CMS Issues FY 2013 Proposed Rule: Hospital Inpatient Prospective Payment System	1
Intellectual Property Awareness Assessment Tool	2
What is the QSR?	2
ICD-10 Compliance Delayed One Year by HHS	2

Q2-2012 Orthopedic Roundup Today News Articles 2-3

Clinical, Regulatory, IP, Compliance, Reimbursement	2
Finance, M&A & Other Corporate Transactions	3
Technology, Product & Industry	3
Operational, HR & Other	3

Q2-2012 Orthopedic Panel 510(k) Clearances 3-6

Q2-2012 Orthopedic Advisory Premarket Approval (PMA) Approvals 6

Patient Protection and Affordable Care Act: An Effort to Lower Cost and Reduce Waste

Jun. 1, 2012

by *Daria Harlin, J.D. and Blair Burnett*

The main topic of discussion at a recent American Health Lawyers Association (AHLA) conference held in Washington, DC focused on initiatives to reduce overall costs to the healthcare system, and how the pending Patient Protection and Affordable Care Act (PPACA) will further this goal of lowering the cost impact, while providing optimal care to patients.

What is the PPACA?

PPACA, also known as the 'Affordable Care Act,' is a complex piece of legislation aiming to improve U.S. healthcare as a whole, with a primary goal of decreasing cost by reducing waste in the healthcare industry. Many speculate that waste accounts for 20-30% of current healthcare costs, and that this waste is costing the government and the tax payer billions of dollars per year. PPACA relies on two initiatives to lower costs and reduce waste: (1) The "Sunshine" provision and (2) Comparative Effectiveness Research (CER).

Federal Sunshine Act

PPACA progresses and reiterates the trend of the last decade to provide more transparency in healthcare transactions by mandating disclosure of all

financial interactions between the healthcare provider and the device/drug manufacturer. According to PPACA, beginning on January 1, 2013 all medical device and pharmaceutical companies will have to disclose and report to CMS all payments and transfers of value to physicians. The form of the payments, e.g., cash, stock, stock options, services will have to be reported, along with the nature of the payment e.g., consulting fees, gifts, food, travel, entertainment, charitable donations. Failure to disclose such information to CMS will result in civil monetary penalties. Additional information on specific requirements and penalties is available online.

Upon receiving the reported information, CMS will create a database accessible to the public including all of the disclosed data. A patient will be able to see exactly how much payment, if any, their physician has received from certain companies. This transparency will allow the patient to make a much more informed decision about their medical needs, which in turn will reduce the waste associated with healthcare costs.

What does Sunshine mean for you?

Medical device companies will have to start tracking and reporting payments to CMS starting January 2013. This topic has been discussed before in a previous MCRA blog post by MCRA Healthcare Compliance Vice President, Christopher Gingras: Preparing for Next Year's Patient Protection Affordable Care Act Disclosures. [Read More](#)

CMS Issues FY 2013 Proposed Rule: Hospital Inpatient Prospective Payment System

May.25.2012

by *Daria Harlin, J.D.*

Late last week, the 2013 Inpatient Prospective Payment System (IPPS) Proposed Rule appeared in the May 11, 2012 edition of the *Federal Register*. This Proposed Rule intends to revise and update the Medicare hospital inpatient prospective payment system for acute care hospitals and for inpatient services provided by long-term care hospitals for fiscal year 2013. MCRA has reviewed the major changes and potential revisions and has provided a synopsis below. A more comprehensive analysis specifically detailing the Proposed Rule's impact on the orthopedic industry is forthcoming.

The Center for Medicare and Medicaid Services (CMS) issued the FY 2013 Proposed Rule late last month; changes under the rule would be applicable to discharges occurring after October 12 of this year. This rule intends to modify and update the Medicare fee-for-service inpatient payment rates and policies and also continues to implement certain key provisions of the Patient Protection and Affordable Care Act (PPACA). Notable provisions of the rule include:

- Medicare payments to general acute care hospitals are projected to increase 0.9 percent, while hospitals that successfully participate in the Hospital Inpatient Quality Reporting Program would receive a 2.3 percent increase in payment from CMS. This latter figure accounts inflation, a statutorily mandated adjustment factor and increases related to coding changes and hospital documentation;
- Two new conditions may be added to CMS's list of Hospital-Acquired Conditions (HACs), related to Surgical Site Infection. The first specifically relates to the implantation of a cardiac medical device: Surgical Site Infection following cardiac implantable electronic device (CEID). Under the HAC provision, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission. Thus, if this proposed change is effected in the Final Rule... [Read More](#)



Orthopedic Intelligence

Specializing in the Neuro-Musculoskeletal Industry

Clinical • Regulatory • Reimbursement • Quality Assurance • Intellectual Property • Healthcare Compliance

Intellectual Property Awareness Assessment Tool

May.8.2012

by **Andy Riutta**

“Do any of the products that you produce or plan to market have unique design elements that you consider to be important to your product differentiation?”

This is a question posed by a [new online tool](#) released by the U.S. Patent and Trademark Office (USPTO) to “help manufacturers, small businesses, entrepreneurs and independent inventors easily assess their knowledge of intellectual property (IP).” The assessment guides you through a set of 62 questions to help you investigate your position with respect to trademarks, copyrights, design patents, trade secrets, utility patents, using technology of others, licensing technology to others, international IP rights and IP asset tracking. Upon completing the assessment, you will receive a customized set of IP strategies and best practices based on your responses.

If your answer to the question above was yes, you may benefit from obtaining a design patent. A design patent differs from its more well-known cousin the utility patent in that the design patent protects the look of a product while a utility patent protects how it is used or works. To continue reviewing your IP position, check out the [full assessment](#) for more great questions.

If this assessment raises issues that you would like to address, we at MCRA would welcome the opportunity to help. We provide high quality patent searches for medical devices and other medical technologies and are always happy to discuss your search requirements and give you a complimentary quote.

What is the QSR?

Apr.30.2012

by **Patrick Biggins**

Many individuals new to the medical device industry in the United States may be confused when they hear the acronym QSR. The Food and Drug Administration (FDA) Quality System Regulation (QSR) is based on the Federal Food, Drug and Cosmetic Act, otherwise known as The Act in our industry. The Act is contained in the United States Code (i.e., federal laws), the laws passed by the United States Congress. The QSR can be found in the Code of Federal Regulations (CFR) which is periodically updated and published by Congress. The actual location for the QSR is The Code of Federal Regulations, Title 21 – Food and Drugs, Part 820. In our industry this is commonly abbreviated by [21 CFR Part 820](#).

QSR is often called current good manufacturing practices and is the basis used by FDA to perform a facility inspection following the Quality System Inspection Technique (QSIT). As the name implies, QSR is the regulation for medical devices. Quoting from the regulation, “this part establishes basic requirements applicable to manufacturers” Manufacturers of class II and class III (and certain class I) medical devices sold in the United States are required to comply with this regulation. The regulation states it is to be applied to any finished device “manufactured, imported or offered for import” And most importantly the regulation has requirements “intended to ensure that finished devices will be safe and effective” What this means is if the medical device is to be available for sale in the United States, the manufacturer must meet the requirements in the regulation. [Read More](#)

ICD-10 Compliance Delayed One Year by HHS

Apr.10.2012

by **Carolyn Neumann, CPC**

The U.S. Department of Health and Human Services (HHS) announced on April 9, 2012 that the compliance date for medical providers to begin using the new ICD-10 diagnosis and hospital procedure reporting code system will be pushed up one year to October 1, 2014.

HHS PROPOSES ONE-YEAR DELAY OF ICD-10 COMPLIANCE DATE with a proposed rule to postpone the date after pressure from some health industry groups. HHS had disclosed in February that it was evaluating the deadline and alluded to this extension for required compliance. The industry has been preparing for this change for years however recent polls have shown that up to half of healthcare providers did not know when they would complete their impact assessment or know when their testing of the new systems would occur.

Providers, having recently navigated the 5010 migration for reporting standards, may not have been able to use their full resources needed for ICD-10 compliance. Not all providers are happy with the decision and those who had ramped up for the change now will need to extend resources further to incorporate the delay. In the end, with extensions or not, the change will bring both positive and negative impacts to the already intricate business of medical reporting standards

Top Orthopedic Roundup Today News Articles during Q2, 2012

Clinical, Regulatory, IP, Compliance, Reimbursement

1. Medsafe announces recall of hip implant device
2. Histogenics' NeoCart for Patients with Knee Cartilage Damage Demonstrates Continued Efficacy for Periods of Up to Five Years
3. Paradigm Spine, LLC Announces Landmark Results In Two Recent Publications Based On Its Groundbreaking coflex® IDE Study
4. Spinal Kinetics Wins Another Round in Synthes' Patent Litigation
5. KFx Medical Corporation Announces Notice of Allowance from United States Patent Office for Fourth Double Row Patent Used in Orthopedic Sports Medicine
6. MEDICREA's LigaPASSTM: FDA Approval and First Surgeries in the US
7. House votes to approve FDA funding bill
8. FDA's \$6.4B drug, device review fee plan passes US Senate
9. Texas Workers Compensation Dept. Adopts Medical Treatment Guidelines Recommending STAR™ Ankle Replacement System Exclusively
10. FDA issues final rule on sterility testing of biological products (May)
11. Legislation to establish medical device regulatory framework advances in Malaysia
12. LDR Announces FDA Clearance and Launch of the ROI-C® Lordotic Cervical Cage
13. Medsafe announces recall of hip implant device
14. VertiFlex®, Inc. Announces Five New Key U.S. Patent Awards
15. TransCorp Spine Receives FDA 510(k) Clearance for the SpinePort(tm) Spinal Access System for Minimally-Invasive Access and Visualization of the Cervical Spine



Orthopedic Intelligence

Specializing in the Neuro-Musculoskeletal Industry

Clinical • Regulatory • Reimbursement • Quality Assurance • Intellectual Property • Healthcare Compliance

Finance, M&A & Other Corporate Transactions

1. Johnson & Johnson Announces Completion of Synthes Acquisition
2. Biomet Announces Initial Closing of DePuy Trauma Acquisition
3. Precision Spine Acquires Spinal USA, LLC & Precision Medical of Mississippi, LLC
4. Mindray Medical to Acquire Controlling Stake in Dragonbio's Orthopedics Business for US\$35.5 Million
5. SurgLine International, Inc. Signs Three Year Agreement To Provide Rural California Area Patients With Its Orthopedic Spinal Implant Product, Parties Project \$4 Million In Revenues Over Life Of Agreement
6. Regenerative Sciences Receives \$2M Investment for Orthopedic Stem Cell Initiatives
7. Amendia, Inc. and Medline Industries, Inc. Announce Investment and Strategic Business Alliance
8. New products, new customers jumpstart sales for OICMAKO Surgical Corp. Reports Operating Results for the First Quarter 2012 and \$50 Million Debt Funding Commitment
9. Smith & Nephew climbs after restructuring starts to pay off
10. OrthoSensor closed on an additional US \$15MM in Series B Preferred Stock financing to support commercialization of the OrthoSensor™ Knee Balancer
11. ArthroSurface reaches \$100M mark
12. Foundation Announces Funding of Educational Grants to Advance Orthopaedic Practice
13. NeuroLogica Corporation Announces Partnership with Stryker
14. Medical Device Component Manufacturer MRPC Continues Expansion with Acquisition of ETI
15. Advanced Biologics Awarded Supplier Agreement with Premier Healthcare Alliance for OsteoAMP® Product Line

Technology, Product & Industry

1. Smith & Nephew launches two plating systems for foot and ankle surgeons at AOFAS annual meeting in San Diego
2. Pentagon's Prosthetic Plan: Tap Spinal Fluid to Fuel Fake Limbs
3. SANUWAVE Technology Shown to Prevent Osteoarthritis Onset Over Time
4. Histogenics Announces Publication in Journal of Bone and Joint Surgery Demonstrating that NeoCart® is Associated with Greater Clinical Efficacy Two Years After Treatment than Current Standard of Care, Microfracture Surgery
5. Smith & Nephew: Voluntary Market Withdrawal of Hip Component
6. Zimmer Introduces a new Porous Metal Interbody Implant for Lumbar Spine at SpineWeek 2012
7. Newly formed Safe Orthopaedics to revolutionize the cost effectiveness, safety, traceability and efficiency of orthopaedic and spinal implant systems
8. Mazor Robotics Introduces Renaissance C-OnSite Application for 3D Intra-Operative Implant Verification
9. OMNIlife science, Inc. Announces the Successful Completion of 1000 Knee Replacements Utilizing OMNI's APEX Robotic Technology ("A.R.T.™")
10. Biomedical Structures Introduces Breakthrough Medical Textile Weaving Capabilities for Artificial Tendon and Ligament Applications

11. Smith & Nephew launches revolutionary open-architecture suture anchor for rotator cuff repair with greater pullout strength than competitors
12. Scoliosis Effectively Treated With Magnetically Controlled Growing Rods - No Repeat Invasive Surgery Required
13. Amedica Corporation Launches Dynamic Bone™ and DryFlex Allograft Products
14. New Independent Survey of U.S. Foot and Ankle Surgeons Affirms Market Leadership of STAR™ Total Ankle Replacement
15. No link found between metal-on-metal hip replacement and cancer risk

Operational, HR & Other

1. US House votes to kill Obama's medical device tax
2. Survey blames FDA for eroding med-tech
3. Medical device maker NuVasive plans to invest \$75 million, add 17 jobs in Memphis operation
4. Orthofix to pay \$42M to settle felony bone growth charges
5. U.S. House panel backs medical device tax repeal
6. Details emerge on ex-Stryker CEO MacMillan's departure
7. MDT to cut 1,000 in slowing markets; 1,500 to be added mainly overseas
8. Smith & Nephew eyes Brazil as \$150 million market
9. SurgLine International, Inc. Launches A Wholly Owned Operating Subsidiary To Pursue Cost Containment Strategies
10. University of Akron Entrepreneurs Win Launch Town Award for Spinal Implant
11. Arthrex breaks ground
12. Tornier Announces 2012 Facility Consolidations
13. Biobank aims to collect stem cells and tissues for use in future bone grafts
14. Bradshaw Medical to expand in Kenosha, add up to 100 jobs
15. TransCorp Spine Names Christopher Welch President and Chief Executive Officer

Search the [510\(k\) Premarket Notification Database](#) for more information on the below clearances

Q2-2012 Orthopedic Panel 510(k) Clearances

Joint

Device Name	Applicant	510(k) #	Decision Date
ascend shoulder system32	tornier, inc.	K12149333	6/20/12
synthes radial head prosthesis system36	synthes usa, llc	K11203037	6/19/12
linear porous coated hip stem, size 5; r40	encore medical, l.p.	K12102441	6/19/12
synthes va lcp ankle trauma system42	synthes usa	K12085443	6/18/12
signature planner,signature guides50	materialise n.v.	K11186351	6/15/12
renovis surgical hip joint replacement p36	renovis surgical technologies, llc	K11289737	6/13/12



Orthopedic Intelligence

Specializing in the Neuro-Musculoskeletal Industry

July 2012

Clinical • Regulatory • Reimbursement • Quality Assurance • Intellectual Property • Healthcare Compliance

Joint			
Device Name	Applicant	510(k) #	Decision Date
deput delta xtend reverse shoulder40	deputy france	K12017441	6/11/12
amistem and quadra - line extension42	medacta international	K12101143	6/8/12
gmk - line extension44	medacta international	K12079045	6/8/12
makoplasty total hip application, rio st54	mako surgical corporation	K12106455	6/6/12
vivacit-e vitamin e highly crosslinked p62	zimmer, inc.	K12037063	6/4/12
smr resurfacing shoulder system- humeral64	limacorporate s.p.a.	K11290065	6/1/12
optetrak logic cr tibial insert, size 0 66	exactech, inc.	K12130767	5/31/12
si-fix sacroiliac joint fusion system74	medtronic sofamor danek	K11047275	5/29/12
compress(r) segmental humeral replacemen84	biomet orthopedics llc.	K11290585	5/24/12
lucent or lucent magnum86	spinal elements, inc.	K11063287	5/23/12
taper set hip system rdp stem92	consensus orthopedics, inc.	K12126393	5/22/12
dyna locking ankle nail94	u&i corp.	K12041995	5/21/12
metal-on-metal hip systems-additional co98	biomet manufacturing, inc.	K11327199	5/18/12
genesis ii ps non-modular femoral compon104	smith & nephew, inc.	K120698105	5/18/12
vanguard ssk 360 revision knee system108	biomet manufacturing corp.	K121149109	5/16/12
modulus stems, modulus necks, modular fe116	limacorporate s.p.a.	K112158117	5/10/12
synthes variable angle lcp elbow system 128	synthes usa	K120717129	5/8/12
"united" u2 femoral component, ps, #7132	united orthopedic corporation	K120507133	5/4/12
metafix femoral stem for hemi-arthroplas136	corin u.s.a.	K120362137	5/4/12
lospa tibial base plate142	corentec co., ltd	K121037143	5/3/12
osteobridge ika knee arthrodesis nail wit148	merete medical gmbh	K120978149	5/2/12
single-site medium-large clip applier, s158	intuitive surgical, inc.	K120215159	4/30/12
r3 xlpe liners160	smith & nephew, inc.	K113848161	4/27/12
osteomed wrist plating system174	osteomed lp	K120015175	4/24/12
neo cr knee system182	pipeline orthopedics	K120313183	4/20/12
itotal cruciate retaining (cr) knee repl184	conformis, inc.	K120316185	4/19/12
modular proximally fluted hip stem190	smith & nephew, inc.	K113789191	4/19/12

Joint			
Device Name	Applicant	510(k) #	Decision Date
versafitcup cc trio-additional liners220	medacta international	K120531221	4/18/12
ascend shoulder system234	tornier, inc.	K120794235	4/13/12
titan modular total shoulder system238	ascension orthopedic	K112438239	4/11/12
first choice druj system, partial head i246	ascension orthopedic	K112481247	4/9/12
2gc hip/knee modular spacer254	mandell horwitz consultants llc	K112470255	4/5/12
zimmer patient specific instrument syste262	materialise n.v.	K113829263	4/2/12
anatomic ankle arthrodesis interlocking 264	small bone innovations inc.	K112982265	4/2/12

Spine			
Device Name	Applicant	510(k) #	Decision Date
xia 4.5 spinal system30	stryker corp	K12134231	6/22/12
blue mountain cervical plate34	qualgenix llc	K11280935	6/20/12
op spine system38	orthopediatrics, corp.	K12125039	6/19/12
tm-400 device44	zimmer trabecular metal technology, inc.	K12020345	6/15/12
medysy lt cage system46	medyssey co., ltd.	K12124647	6/15/12
polaris spinal system-ballista spinal ro48	biomet spine	K12113049	6/15/12
expedium spine system, viper system, vip52	deputy spine, inc.	K11113653	6/14/12
revere 4.5 stabilization system54	globe medical, inc.	K11339555	6/14/12
honour spacer system30	nexxt spine llc	K120345	6/13/12
spineology peek lumbar interbody fusion	spineology, inc.	K121129	6/13/12
spinevision lumis(tm) cannulated polyaxi50	spinevision, s.a.	K11260751	6/7/12
capsure(r) ps system52	spine wave, inc.	K12064653	6/7/12
stainless steel spinal system68	theken spine, llc	K12082969	5/30/12
tm ardis interbody system tm ardis inter70	zimmer trabecular metal technology	K11356171	5/29/12
range spinal system, unit rod78	k2m, inc.	K12089979	5/25/12
synthes acis/vertebral spacer cr80	synthes (usa) llc	K12027581	5/25/12
lexus cervical intervertebral body fusio82	l&k biomed co., ltd	K12084083	5/24/12
tempus cervical plate system88	neurostructures, llc	K12051589	5/23/12



Orthopedic Intelligence

Specializing in the Neuro-Musculoskeletal Industry

Clinical • Regulatory • Reimbursement • Quality Assurance • Intellectual Property • Healthcare Compliance

Spine			
Device Name	Applicant	510(k) #	Decision Date
lexus cervical fixation system90	l & k biomed co., ltd	K12087991	5/23/12
synthes matrix system96	synthes spine	K12092897	5/18/12
r&d innovation pedicle screw system100	r&d innovation, llc	K120091101	5/18/12
range spinal system (mesa and denali)102	k2m, inc.	K120099103	5/18/12
s 100 pedicle screw system110	renovis surgical technologies, llc	K111940111	5/15/12
synthes uss connector112	synthes spine	K120571113	5/14/12
dss stabilization system-rigid120	paradigm spine, llc	K120491121	5/9/12
synster pedicle screw system synster plu122	bm korea co., ltd.	K120353123	5/9/12
reliance cervical ibf system124	reliance medical systems, llc	K120396125	5/8/12
plateau spacer system126	life spine	K121116127	5/8/12
pioneer lateral plate system130	pioneer surgical technology, inc	K120724131	5/7/12
viper system140	depuy spine, inc.	K121020141	5/3/12
ayers rock cervical cage152	qualgenix	K112801153	5/1/12
mont blanc pedicle screw systems154	qualgenix	K112684155	5/1/12
lateral fusion device156	integra spine (integra lifesciences)	K112986157	5/1/12
depuy pulse cervical cage system164	medos international sarl	K120517165	4/26/12
solitaire-c cervical spacer system166	ebi, llc	K113796167	4/26/12
sintea plusstek pls multi-axial screws170	sintea plastek, llc	K112611171	4/25/12
venus lumbar intervertebral body fusion 188	l&k biomed co., ltd	K120063189	4/19/12
nextgen altius oct system222	biomet spine (aka ebi, llc)	K113593223	4/17/12
op spine system226	orthopediatrics, corp.	K120291227	4/16/12
transcorp spinal access system228	transcorp, inc.	K113352229	4/16/12
escalate laminoplasty system230	stryker spine	K113802231	4/16/12
caplox ii pedicle screw system232	captiva spine, inc	K120292233	4/13/12
plymouth thoracolumbar plate system236	globus medical inc.	K120092237	4/13/12
capstone control spinal system244	medtronic sofamor danek usa, inc.	K120368245	4/9/12
cervical plate248	eisertech, llc	K113170249	4/6/12

Spine			
Device Name	Applicant	510(k) #	Decision Date
choice spine vertebral body replacement 252	choice spine, lp	K120570253	4/5/12
everest spinal system256	k2m, inc.	K120656257	4/4/12
securis spinal fixation260	cumtom spine	K113361261	4/3/12
tiger spine system268	corelink llc	K120696269	4/2/12

Trauma			
Device Name	Applicant	510(k) #	Decision Date
mini maxlock extreme plating system34	orthohelix surgical designs, inc.	K12143735	6/13/12
ncb periprosthetic trochanter plates and38	zimmer gmbh	K12077239	6/12/12
appianfx suture anchor (6mm) (5mm) appia46	kfx medical	K12084147	6/7/12
smith & nephew, inc. external fixation s48	smith & nephew, inc.	K12087149	6/7/12
citieffe-titanium cannulated screw56	citieffe	K11338857	6/5/12
synthes 3.5 mm va-lcp proximal tibia pla60	synthes (usa) products llc	K12068961	6/4/12
trilliant surgical k-wires58	trilliant surgical ltd	K12100859	6/4/12
ortho solutions trauma plates for osteos72	ortho solutions limited	K12036073	5/29/12
i-fuse hammer toe systems76	orthopro llc	K11300677	5/25/12
mini cannulated headed and headless scre106	instratek, inc.	K120493107	5/17/12
healix advance peek anchor114	depuy mitek sarl, a johnson and johnson	K120449115	5/11/12
eos small bone fixation system118	trimed, inc.	K112794119	5/10/12
kensey nash bone void filler xc134	kensey nash cororation	K120141135	5/4/12
ortholoc 3di hallux system138	wright medical technology, inc.	K120359139	5/3/12
force medical im nail system144	force medical, inc	K102577145	5/3/12
microware bone plates and bone screw146	microware precision co., ltd.	K111008147	5/2/12
external fixator st.a r 90 f4150	citieffe	K113384151	5/1/12
aptus proximal humerus system162	medartis ag	K120108163	4/27/12
variax superior and anterior, lateral an168	howmedica osteonics corp dba stryker ort	K113760169	4/25/12
pro-toe(tm) vo hamertoe implant system-l172	wright medical technology, inc.	K120645173	4/24/12



Orthopedic Intelligence

Specializing in the Neuro-Musculoskeletal Industry

Clinical • Regulatory • Reimbursement • Quality Assurance • Intellectual Property • Healthcare Compliance

Trauma

Device Name	Applicant	510(k) #	Decision Date
apex kirschner wires and steinmann pins178	apex tools & orthopedics co.	K121004179	4/24/12
parcus twist 4 5mm peek suture anchor, p180	parcus medical, llc	K120942181	4/20/12
otis-c plus186	science for biomaterials	K120818187	4/19/12
intraosseous fixation system224	orthohelix surgical designs, inc.	K120165225	4/17/12
mini maxlock extreme plating system240	orthohelix surgical designs, inc.	K120157241	4/10/12
solafix twist screw implant system, surg242	solana surgical llc	K120390243	4/10/12
nanofuse dbm250	nanotherapeutics	K120279251	4/6/12
vlp 2.7mm extra large percutaneous calca258	smith & nephew, inc.	K120667259	4/4/12
ortholoc(tm) 3di locking screws ortholoc266	wright medical technology, inc.	K120802267	4/2/12

Trauma

Device Name	Applicant	PMA #	Decision Date
ULTRASOUND BONE HEALING S	bioventus llc	P900009 S033	6/6/12
EUFLEXXA (1% SODIUM HYALU	ferring pharmaceutic	P010029 S015	5/4/12
GEL-ONE	seikagaku corp.	P080020 S001	5/4/12
SYNVISC & SYNVISC-ONE	genzyme corp.	P940015 S025	5/3/12

Search the [Premarket Approval \(PMA\) Database](#) for more information on the below approvals

Q2 2012 - Orthopedic Advisory Premarket Approval (PMA)

Joint

Device Name	Applicant	PMA #	Decision Date
DURALOC OPTION CERAMIC HI	depu orthopaedics,	P040023 S021	6/15/12
DUROLOC OPTION CERAMIC HI	depu orthopaedics,	P040023 S022	6/15/12
DEPUY CERAMAX CERAMIC TOT	depu, inc.	P070026 S006	6/15/12
PINNACLE COMPLETE ACETABU	depu orthopaedics,	P090002 S004	6/15/12
EXATECH NOVATION CERAMIC	exactech, inc.	P050039 S007	4/27/12
DURALOC OPTION CERAMIC HI	depu orthopaedics,	P040023 S020	4/26/12
EXACTECH NOVATION CERAMIC	exactech, inc.	P050039 S009	4/26/12
DEPUY CERAMAX CERAMIC TOT	depu, inc.	P070026 S005	4/26/12
PINNACLE COMPLETE ACETABU	depu orthopaedics,	P090002 S003	4/26/12
CERAMTEC CERAMIC TRANSCEN	ceramtec ag	P010001 S009	4/19/12
DEPUY PINNACLE COMPLETE A	depu orthopaedics,	P090002 S002	4/17/12

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.

Information within this newsletter is provided by MCRA for informational purposes only. Information should not be relied upon, but rather stimulate further review and research. MCRA is not a law firm and does not provide legal advice. For questions or comments regarding MCRA and/or MCRA’s Orthopedic Intelligence Newsletter, please contact Elizabeth Baldacchino, at ebaldacchino@mcra.com or by calling (202) 552-5811.



Musculoskeletal Clinical
Regulatory Advisers, LLC